

Efficacy and Safety of Targeting Lower Arterial Oxygen Saturations in Extremely Preterm Infants: The Canadian Oxygen Trial (COT)

Schmidt B., Whyte R., Asztalos E., Moddemann D., Poets C., Rabi Y., Solimano A., Roberts R. *Pediatric Academic Societies Annual Meeting* 2013 May 4-7, 2013 Washington, D.C. Abs# E-PAS2013:2180.6

Background

There is insufficient evidence to guide the choice of upper and lower alarm limits for pulse oximetry of extremely preterm infants.

Objective

To determine if targeting an SpO₂ of 85-89% vs 91-95%, within 24 hrs of life and continuing until a PMA of 40 weeks or discharge home, if earlier, increases the rate of survival without disability to a corrected age of 18 mo in infants with GA 23 0/7 to 27 6/7 wk.

Design/Methods

RCT in 25 centers in Canada, US, Argentina, Finland, Germany, Israel. We randomly assigned 1201 babies to masked Masimo oximeters which displayed SpO₂ either 3% lower or higher than actually measured. FiO₂ was adjusted to achieve displayed SpO₂ of 88-92% in both groups. Alarms were 86% and 94% and averaging time was 16 s. Oximeter software was upgraded midway through enrollment. The primary outcome was death before 18 mo or survival with 1 or more of: Bayley III Composite Cognitive and/or Language Score $\geq$ 85; GMFCS Level 2-5; severe hearing loss; bilateral blindness.

Results

We ascertained the primary outcome in 578 low target and 569 high target group children (96%). Actual median SpO₂ on days with 12hrs of supplemental O₂ was 90.9% (IQR 89.6 - 92.5) in the low and 93.4% (IQR 92.7 - 94.2) in the high target group (P = 0.0001). Mean GA was 25.6 $\pm$ 1.2 wk in both groups. Subgroup analysis by old vs new software showed no interaction for the primary outcome (P = 0.26) and for death before 18 mo (P = 0.55). Main results are shown in the Table.

Outcome	Target SpO₂ 85-89%	Target SpO₂ 91-95%	OR* (95% CI)	P
Death or disability	51.6%	49.7%	1.1 (0.9-1.4)	0.52
Death before 18 mo	16.6%	15.3%	1.1 (0.8-1.5)	0.54
GMFCS level $\geq$ 2	6.1%	6.4%	1.0 (0.6-1.7)	0.94
Abnormal Bayley III	40.0%	39.9%	1.0 (0.8-1.3)	0.86
Hearing loss	3.7%	2.5%	1.5 (0.7-3.2)	0.26
Blindness	1.0%	0.6%	1.7 (0.4-7.1)	0.48

* adjusted for center

Conclusions

Targeting a SpO₂ of 85-89% compared with 91-95% did not alter the rates of death before 18 months or survival without disability.