

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

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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 (Pint 0.26) and for death before 18 mo (Pint 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.