

Outcomes at Hospital Discharge in the BOOST II Trials of Neonatal Oxygen Saturation Targeting

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Background

Five RCTs are comparing the effects of targeting oxygen saturation (SpO₂) ranges of 85 - 89% vs 91 - 95% on disability-free survival in infants <28 weeks gestation, using masked, offset Masimo oximeters. Interim analysis of the 3 BOOST II trials showed that the high target increased 36 week survival in infants managed after the oximeter calibration software had been revised.¹

Objective

Report outcomes to hospital discharge overall and with old or new oximeter software.

Design/Methods

Pooled analysis of hospital outcomes.

Results

Overall, targeting 91-95% increased ROP and decreased surgical or fatal NEC. Mortality was not significantly different. There was significant heterogeneity in the effect of oxygen targets on mortality between old and new oximeter software ($p = 0.006$ on test for interaction), but not for other outcomes. In infants managed with oximeters using new software, targeting 91-95% increased survival ($p = 0.001$), but had no significant effect on ROP treatment or O₂ treatment at 36 weeks.

Conclusions

Targeting saturation 91-95% was associated with survival advantage. Whilst awaiting 2 year follow up it appears wise to avoid a saturation target of 85-89% in infants <28 weeks gestation.

Hospital outcomes of infants by SpO ₂ target overall				
	SpO ₂ 85-89%	SpO ₂ 91-95%	Relative Risk (95% CI)	p value
Death in hospital	235/1219 (19.3%)	202/1217 (16.6%)	1.16 (0.98 - 1.38)	0.09
Treated for ROP	110/1125 (9.8%)	141/1124 (12.5%)	0.78 (0.62 - 0.99)	0.04
Severe IVH	140/1203 (11.6%)	126/1211 (10.4%)	1.12 (0.89-1.40)	0.33
Surgical or fatal NEC	127/1222 (10.4%)	97/1223 (7.9%)	1.31 (1.02-1.69)	0.04
O ₂ dependency at 36 weeks	394/998 (39.5%)	461/1031 (44.7%)	0.88 (0.80 - 0.98)	0.02

Hospital outcomes of infants pooled by old vs new oximeter calibration software						
	old software			new software		
	SpO ₂ 85-89%	SpO ₂ 91-95%	Risk Ratio (95% CI)	SpO ₂ 85-89%	SpO ₂ 91-95%	Risk Ratio (95% CI)
Death in hospital	98/629 (15.6%)	109/630 (17.3%)	0.90 (0.70 - 1.16)	137/590 (23.2%)	93/587 (15.8%)	1.47 (1.16 - 1.86) §
Treated for ROP	52/574 (9.1%)	61/562 (10.9%)	0.83 (0.59-1.19)	58/551 (10.5%)	80/562 (14.2%)	0.74 (0.54-1.02) ¶

†evidence of highly significant heterogeneity of treatment effect between old vs new software, (test for interaction p=0.005). p = 0.41 §p = 0.001, ||p=0.31, ¶p=0.061.

1. Stenson B, et al. N Engl J Med 2011; 364: 1680-2.