SpO2 Target Range and Alarm Limits

East Bay Newborn Specialists Guideline

Prepared by N Mickas, P Joe

01-31-12

Background:

Inspired oxygen is the most frequently used drug in the neonatal intensive care unit. While life-saving in many infants, the toxicity of oxygen is well established. There are many studies in the medical literature describing the role oxygen and oxidative stress play in diseases such as ROP, chronic lung disease, and some concern over an increased incidence of leukemia in newborns exposed to oxygen.

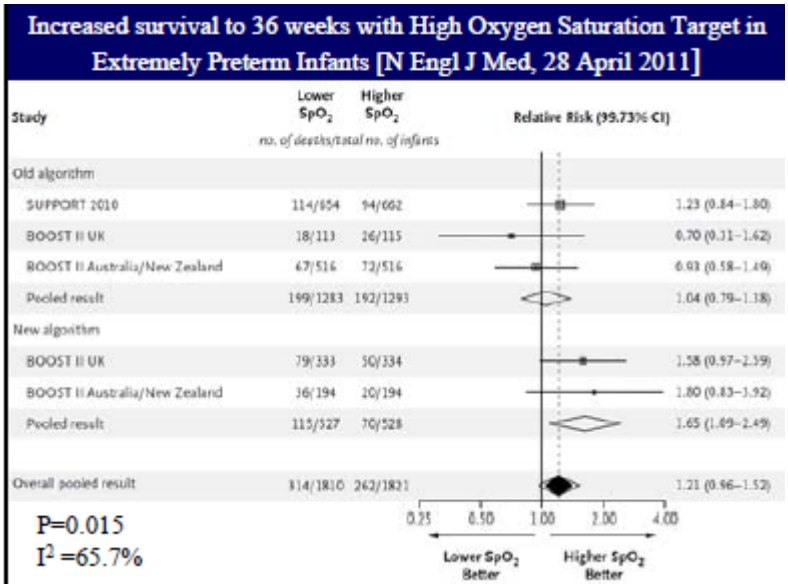
Several studies which have looked at exposure to SpO2 ranges above what are currently used have uniformly showed worse outcomes without any significant benefits. The British BOOST trial and NICHD STOP-ROP trial randomized premature infants to saturations > 95% in hopes of altering neurodevelopmental outcome, and modulating pre-threshold ROP. While no statistically significant benefit was found, both high SpO2 groups had significant morbidities including CLD exacerbations, longer exposure to oxygen, and pneumonia.

Descriptive studies by Tin, and Chow showed that limitation of oxygen exposure, and tolerance of lower SpO2 appears to decrease the incidence of ROP, and had no significant impact on either survival or neurodevelopmental outcome. These studies were small and retrospective, but suggest that limitation of oxygen exposure decreases the incidence of oxygen related diseases, most notably ROP. This led to a fairly consistent tolerance of SpO2 in the mid-80%s as a community standard, despite the lack of well performed, large trials.

The next generation of "Oxygen Trials" considered oxygen levels within what most of us would consider the standard range of 85-95. Three separate studies were undertaken in the US and abroad, with very similar designs (intentionally so, for the sake of later meta-analysis.) The NICHD funded SUPPORT trial, the UK BOOST II trial, and the Australian BOOST II trial. All three studies randomized infants 24-27 6/7 weeks to saturations of either 85-89% or 91-95%. Caregivers were blinded to saturations by control of the pulse oximeters to read 3% high in the low saturation group, and 3% low in the high saturation group, with actual saturations presented if saturations <85%, or >95%. Studies considered a combined outcome of death or ROP, and long term outcomes of death or neurodevelopmental disability.

The SUPPORT trial, published in 2010, demonstrated no significant difference in the composite outcome of death or ROP. In considering each variable, there was a statistically significant decrease in ROP in the low saturation group, but there was also a statistically significant increase in death in the low saturation group. The 18 month neurodevelopmental outcome data from SUPPORT was presented in December 2011, and showed that there was not a significant impact on the combined outcome of death or neurodevelopmental disability. However the independent outcome of death was statistically significantly higher in the low SpO2 group. Incidentally, despite an increased incidence of ROP, there was not a significant difference in either blindness, or visual limitation between the groups. Although this data has been presented, it is not yet published.

Although not yet published in its entirety, the BOOST II trials were stopped early by the data safety and monitoring committee for a similar increase in mortality in the low saturation group. A meta-analysis of the oxygen trials, with a Forest plot, to 3 standard deviations can be seen below.



Given the clear evidence of morbidity with SpO2 > 95%, and the apparent increase in mortality in infants with SpO2 target range <89%, we suggest that all infants requiring supplemental O2 should be managed with a target SpO2 range of 89-94%. Note that this recommended range may change as more details of these and other trials are published.

It is critical to avoid extended periods of hyperoxia, but may be equally harmful to allow extended periods of modest hypoxia. The exact cause of the increase in mortality seen in these studies remains unclear. Discussion continues as to whether the time with saturations in range is the etiology of risk or whether the significantly increased time spent with saturations <80%, and <70% in the low saturation group led to the mortality increase.

SpO2 Target Range:

- SpO2 target range 89-94 for all NICU Admits on O2 (unless ordered otherwise)

SpO2 Alarm Limits:

- SpO2 alarm limits 89-94 for all NICU Admits on O2 (unless ordered otherwise)

Special Consideration:

- Some patients may be managed with slightly different SpO2 targets and alarm limits
- Note that the data reviewed above was from studies of VLBW infants. The data on the ideal SpO2 range for near-term and post-term infants, or for infants with significant pulmonary hypertension is even less clear than for VLBW infants.

Strategies for maintaining SpO2 within Target Range:

For ALL saturations OUTSIDE the ordered SpO2 Target Range:

- Press PAUSE to silence the monitor for three minutes
- Remain at bedside until SpO2 STABLE within Target Range
- Assess
- Intervene PRN
- Adjust FiO2 as described below

- For SpO2 <80 (mild desat):
    - Increase FiO2 2-5% Q2mins prn to reach Target SpO2 Range
    - Remain at bedside for assessment of response until SpO2 stable
    - Once SpO2 reaches 85, wean FiO2 2-5% every 30 seconds or as fast as possible to reach baseline FiO2 while keeping SpO2 within Target Range
    - Remain at bedside until SpO2 stable within Target Range
- For SpO2 <70 (severe desat):
    - Increase FIO2 by 5-10% Q 2 mins prn to reach Target SpO2 Range
    - Remain at bedside for assessment of response until SpO2 stable
    - Once SpO2 reaches 85, wean FiO2 5-10% every 30 seconds or as fast as possible to reach baseline FIO2 while keeping SpO2 within Target Range
    - Remain at bedside until SpO2 stable within Target Range
- For SpO2 >94:
    - Wean FIO2 2-5% every 2 minutes until SpO2 is stable within Target Range
    - Remain at bedside for assessment of response to changes

References:

Askie LM, et al. Oxygen-Saturation Targets and Outcomes in Extremely Preterm Infants. *N Engl J Med* 2003; 349:959.

STOP-ROP Multicenter Study Group. Supplemental Therapeutic Oxygen for Prethershold Retionopathy of Prematurity (STOP-ROP), a Randomized, Controlled Trial. *Pediatrics* 2000;105:295.

Tin W, et al. Pulse oximetry, severe retinopathy, and outcome at one year in babies of less than 28 weeks gestation. *Arch Dis Child Fetal Neonatal Ed* 2001; 84:F106.

Chow LC, et al. Can changes in clinical practice decrease the incidence of severe retinopathy of prematurity in very low birth weight infants? *Pediatric*s 2003; 111:339.

SUPPORT Study Group. Target ranges of oxygen saturation in extremely preterm infants. *N Engl J Med* 2010.