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Created	@May 11, 2023 3:49 AM
Updated	@May 11, 2023 4:35 AM

The INCUBATOR: Research Summary

Measuring Oxygenation in Newborn Infants with Targeted Oxygen Ranges (MONITOR): a randomised crossover pilot study

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Background:

- There is considerable uncertainty about the optimal approach to providing oxygen therapy to preterm infants.
- The NeOProM Collaboration showed that higher (91–95%) rather than lower (85–89%) SpO 2targets reduced mortality and necrotising enterocolitis (NEC), but increased retinopathy of prematurity (ROP) requiring treatment.
- And, at 18-24 mo of age, Meta-analysis showed no difference in the primary composite outcome of death or major disability

- While there is good evidence that targeting extreme preterm infants to SpO 2 91–95% is associated with improved outcome relative to a lower target range, SpO 2 targets higher than 91–95% have not been studied.
- there needs to be a greater understanding of the likely achieved SpO2 and TcPO2 patterns that might be observed if clinical care is targeted to a higher SpO2 range.

Questions:

- The aim of this study was to explore the achieved oxygenation patterns observed when targeting the SpO2 range 92–97% in oxygen dependent preterm infants.

Study Design:

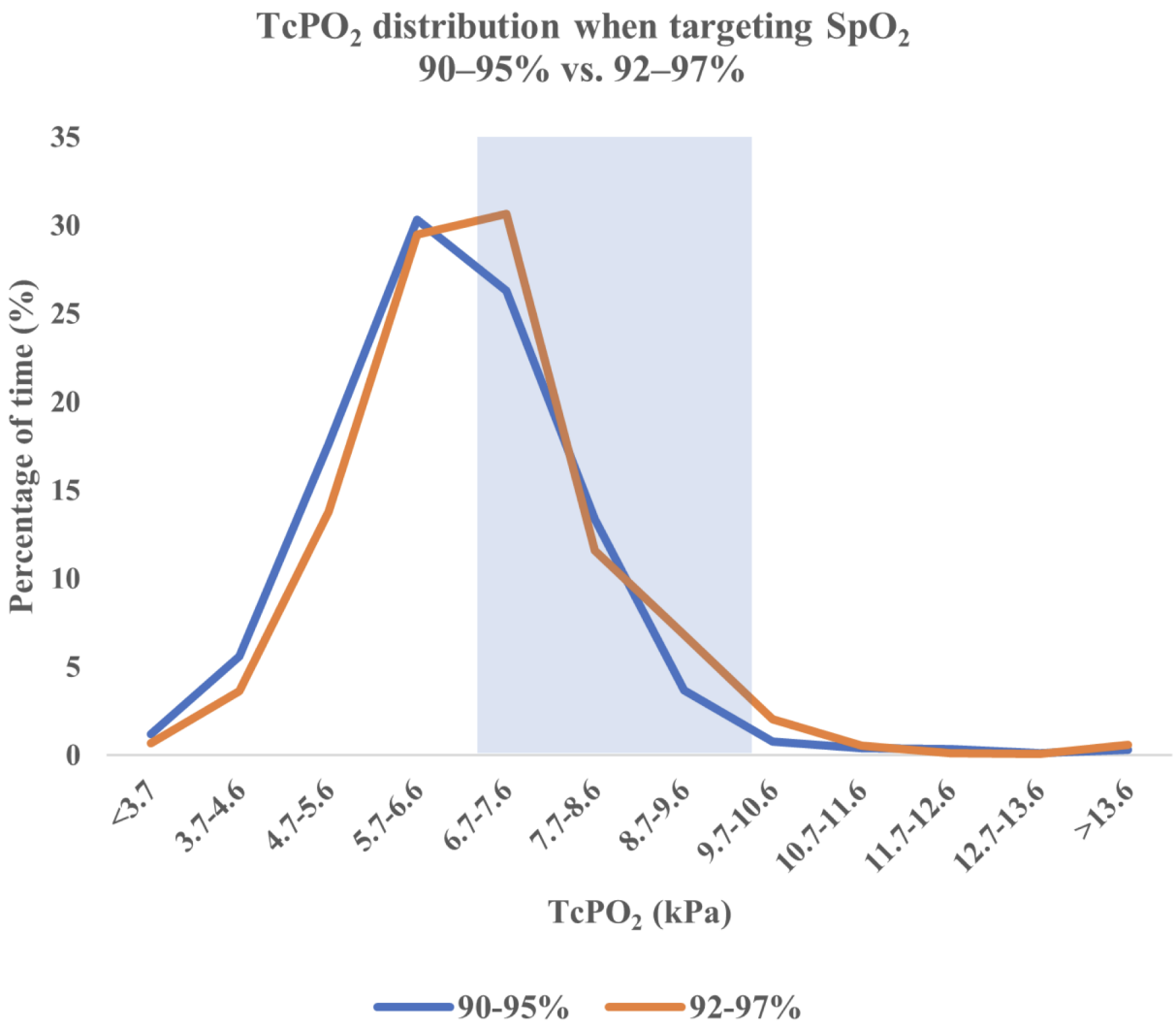
- This was a prospective, single-center, randomized crossover study of two oxygen saturation targets:
  - standard care (90–95%)
  - higher SpO2 target range of 92–97%
- Eligible infants had to be born at less than 29 weeks' gestation, be greater than 48 hours of age and receiving supplementary oxygen.
- Exclusion criteria were congenital anomalies that would impair oxygenation (eg, cardiac defects, congenital diaphragmatic hernia).
- Intervention:
  - Each infant underwent two sequential 6-hour periods where the SpO 2 target range was 90–95% and 92–97%.
  - All FiO 2adjustments were made by the clinical team
  - No wash-out period was included.
  - In both study periods, SpO2 and TcP**O2** were monitored continuously.
- The primary outcomes of the study were the percentage time spent above a SpO2 of 97% and the percentage time spent below a SpO2 of 90%.

- Secondary outcomes included the percentage time with SpO2 <85%, percentage time with SpO 2 <80%, percentage time with TcPO 2 within, above and below 50–80 mmHg and the oxygen variability as measured by SD in TcPO2 and SpO2

Results:

- 20 patients (8 male, 12 female) were studied over a period of two years.
- The median gestation at birth was 26+6 weeks and birth weight 878 g.
- Median study age was 22 days, with median FiO2 at randomisation of 0.29
- At the time of study, 2 of the infants were on SIMV (targeted tidal volume), 8 were on nCPAP and 10 were on HFNC

- With the SpO2 target range 92–97% versus 90–95%, the mean (IQR) percentage time above SpO2 97% was 11.3% (2.7-20.9) versus 7.8% (1.7–13.9), **p=0.02.**
- Percentage time with SpO2 <90% was 13.1% (6.7–19.1) versus 17.9% (11.1–22.4), **p=0.003.**
- Percentage time with SpO2 <80% was 1% (0.1–1.4) versus 1.6% (0.4–2.6), p=0.119.
- When targeted to the SpO2 range 92–97% versus 90–95%, ***there was not a significant difference*** in time spent within, above or below the historically recommended TcPO2 50–80 mm Hg.
- There was no significant difference in variability (SD) of SpO2 (SD 3.7% vs 4%; p=0.274) when targeting SpO2 92–97% versus 90–95%.
- TcPO2 variability was the same between periods (SD 1.2% vs 1.2%; p=0.763). Mean SpO2 was 93.4% and 92.5% (p<0.001). Mean TcPO2 was 6.8 kPa and 6.6 kPa (p=0.257).
- Plots of the cumulative distribution of all pooled SpO2 and PO2 values (figures 1 and 2) show that targeting the SpO2 range 92–97% produced a controlled right shift in SpO 2 and TcPO2 distributions across the whole observed range, without an excess of TcPO2 values above 10.7 kPa (80 mm Hg).



Conclusion:

In conclusion, we have shown that targeting the SpO2 range 92–97% versus 90–95% produced a controlled right shift in SpO2 distribution, with reduced time at SpO2 <90% and increased time with SpO2 above 97% but without increasing time with high TcPO2 (>10.7 kPa). The findings of this study will be useful in the design of a future clinical trial of SpO2 targeting because they show that the SpO2 range 92–97% can be targeted without exposure to severe hyperoxia.

The key question is whether higher SpO2 targets could further reduce mortality in the early weeks after birth, and this has not been studied.