Supplemental Therapeutic Oxygen for Prethreshold Retinopathy Of Prematurity (STOP-ROP) - 2000



Objective

To determine the efficacy and safety of supplemental therapeutic oxygen for infants with prethreshold retinopathy of prematurity (ROP).

Methods

Design: RCT

Sample Size: 649

Treatment Groups:

- 325 to conventional (O2 sat goal: 89-94%)
- 324 to supplemental (O2 sat goal 96-99%)

Outcome Measures:

- Progression to threshold ROP
- Pulmonary exacerbations
- Hospitalization time and complications
- Growth rates and developmental milestones

Results

Point 1: Increased O2 sat goals did not decrease rates of progression to confirmed threshold ROP compared with conventional O2 sat goals

- 48.5% of infants in the conventional arm progressed to confirmed threshold ROP in at least 1 eye, compared with 40.9% in the supplemental
- After adjustment for baseline ROP severity stratum, plus disease, race, and gestational age, the odds ratio (supplemental vs conventional) for progression was .72 (95% confidence interval: .52, 1.01)

Point 2: Supplemental O2 was associated with marginally worse outcomes for pulmonary complications and hospitalization times

- 8.5% of infants in the conventional arm had pulmonary complications compared to 13.2% (p=0.066) in the supplemental arm
- At 50 weeks of postmenstrual age, fewer conventional than supplemental infants remained hospitalized (6.8% v 12.7%), on oxygen (37.0% vs 46.8%), and on diuretics (24.4% vs 35.8%)

Point 3: O2 saturation goals were not correlated with growth rates

• There were no differences between growth rates during the initial first two weeks nor at three months follow-up

TLDR: use of supplemental O2 did not decrease the progression to confirmed threshold ROP; however, was associated with poorer outcomes regarding pulmonary complications and hospitalization time.

The STOP-ROP Multicenter Study Group; Supplemental Therapeutic Oxygen for Prethreshold Retinopathy of Prematurity (STOP-ROP), A Randomized, Controlled Trial. I: Primary Outcomes. *Pediatrics* February 2000; 105 (2): 295–310. 10.1542/peds.105.2.295