

Effect of different oxygen saturation levels on death or disability in extremely preterm infants

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In a randomized trial performed to help resolve the uncertainty about the optimal oxygen saturation therapy in extremely preterm infants, researchers found that targeting saturations of 85 percent to 89 percent compared with 91 percent to 95 percent had no significant effect on the rate of death or disability at 18 months, according to a study published by *JAMA*. The study is being released early online to coincide with its presentation at the Pediatric Academic Societies annual meeting.

"Extremely [preterm infants](#) are monitored with pulse oximeters for several weeks after birth because they may require [supplemental oxygen](#) intermittently or continuously. The goal of oxygen therapy is to deliver sufficient oxygen to the tissues while minimizing oxygen toxicity and oxidative stress. It remains uncertain what values of arterial oxygen saturations achieve this balance in immature [infants](#), who are especially vulnerable to the harmful effects of oxygen," according to background information in the article.

Barbara Schmidt, M.D., M.Sc., of the Children's Hospital of Philadelphia and University of Pennsylvania, Philadelphia, and colleagues conducted a study to compare the effects of targeting lower or higher arterial oxygen saturations in extremely preterm infants on the rate of death or disability. The [randomized trial](#), conducted in 25 hospitals in Canada, the United States, Argentina, Finland, Germany, and Israel, included 1,201 infants with gestational ages of 23 weeks 0

days through 27 weeks 6 days, who were enrolled within 24 hours after birth between December 2006 and August 2010. Follow-up assessments began in October 2008 and ended in August 2012.

Study participants were monitored until postmenstrual ages (the time elapsed between the first day of the mother's last menstrual period and birth [gestational age] plus the time elapsed after birth [chronological age]) of 36 to 40 weeks with pulse oximeters that displayed saturations of either 3 percent above or below the true values. Caregivers adjusted the concentration of oxygen to achieve saturations between 88 percent and 92 percent, which produced 2 treatment groups with true target saturations of 85 percent to 89 percent (n=602) or 91 percent to 95 percent (n=599). Alarms were triggered when displayed saturations decreased to 86 percent or increased to 94 percent. The primary outcome was a composite of death, gross motor disability, cognitive or language delay, severe hearing loss, or bilateral blindness at a corrected age of 18 months. Secondary outcomes included retinopathy of prematurity and brain injury.

The researchers found that targeting lower compared with higher oxygen saturations had no significant effect on the rate of death or disability at 18 months. "Of the 578 infants with data for this outcome who were assigned to the lower target range, 298 (51.6 percent) died or survived with disability compared with 283 of the 569 infants (49.7 percent) assigned to the higher target range," the authors write. "Of the 585 infants with known vital status at 18 months in the lower saturation target group, 97 (16.6 percent) had died compared with 88 of 577 (15.3 percent) in the higher saturation target group."

Targeting lower compared with higher saturations reduced the average postmenstrual age at last use of oxygen therapy, but had no significant effect on any other outcomes, including the rate of severe retinopathy of prematurity.

"Clinicians who try to translate the disparate results of the recent [oxygen saturation](#) targeting trials into their practice may find it prudent to target saturations between 85 percent and 95 percent while strictly enforcing alarm limits of 85 percent at all times, and of 95 percent during times of [oxygen](#) therapy. Our findings do not support recommendations that targeting saturations in the upper 80 percent range should be avoided. Because it is very difficult to maintain infants in a tight saturation target range, such recommendations may lead to increased tolerance of saturations above 95 percent and an increased risk of severe retinopathy. Although no longer a major cause of bilateral blindness, severe retinopathy remains a marker of serious childhood disabilities," the authors conclude.

In an accompanying editorial, Eduardo Bancalari, M.D., and Nelson Claure, M.Sc., Ph.D., of the University of Miami Miller School of Medicine, comment on the findings of this and other studies that have examined this issue.

"[Oxygen therapy](#) continues to present neonatal clinicians with a difficult conundrum where efforts to reduce complications associated with hyperoxemia in premature infants may affect their survival. How the results of these trials should be translated into clinical practice is still controversial. If the long-term outcomes are not affected by the different saturation targets, should the shorter-term outcomes of death, severe retinopathy of prematurity, and bronchopulmonary dysplasia be used to formulate a recommendation? After all, no other outcome is as important as survival. Until the remaining questions raised by these studies are answered by the combined meta-analysis or new evidence becomes available, minimizing extreme oxygenation levels by targeting saturations between 90 and 95 percent appears to be a reasonable approach."

More information: *JAMA*, [doi:10.1001/jama.2013.5555](https://doi.org/10.1001/jama.2013.5555)

JAMA, [doi:10.1001/jama.2013.5831](https://doi.org/10.1001/jama.2013.5831)

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