

Higher oxygen levels improve preterm survival, increase risk for eye condition

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Two findings from an NIH research network study provide new information on how much oxygen very preterm infants should receive starting on the first day of life and the most effective means to deliver it to them.

The first was that higher oxygen levels improve preterm infants' survival but increase the risk for a condition that can damage the retina.

The second was that a treatment typically used for adults with [sleep apnea](#) also is as effective as the traditional ventilator and surfactant therapy used to treat breathing difficulties in preterm infants—and may result in fewer complications. The treatment relies on a continuous positive airway pressure (CPAP) machine to blow air through a preterm infant's nostrils, to gently inflate the lungs.

These findings appear in two articles published online by *The [New England Journal of Medicine](#)*. The study results also will be presented on May 16 at the American Thoracic Society 2010 International Conference in New Orleans.

"Until the current study, CPAP had shown promise in treating respiratory distress in preterm infants, but had never been compared to ventilator therapy in this group of patients," said Alan E. Guttmacher, M.D., acting director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), one of the NIH Institutes that provided infrastructure and funding for the study. "The

study results indicate that CPAP is an effective initial alternative to ventilator therapy for very preterm infants of 24-27 weeks gestational age."

The study was conducted by the 20 academic medical centers participating in the NICHD's Neonatal Research Network. The study also received funding from the NIH's National Heart, Lung, and Blood Institute.

The lead author of the article comparing oxygen saturation levels was Waldemar A. Carlo, M.D., of the University of Alabama at Birmingham. The lead author of the article comparing CPAP therapy to ventilator and surfactant therapy was Neil N. Finer, M.D., of the University of California at San Diego. The NICHD author of both papers was Rosemary D. Higgins, M.D.

"Balancing the benefits of supplemental oxygen against the risks in these very premature babies has been a concern of doctors and parents for decades," said NHLBI Acting Director Susan B. Shurin, M.D., a board-certified pediatrician. "The results of this large clinical trial of extremely low birthweight infants will help inform management decisions to improve chances of survival and reduce complications associated with breathing problems in these vulnerable patients."

The study enrolled 1,316 babies born between the 24th and 27th weeks of pregnancy. A full-term pregnancy is 40 weeks long. The very premature babies in the study had an average weight of less than two pounds.

The study was divided into two arms that provided the findings for the articles. Each arm proceeded at the same time, in the same group of infants. In the first arm, each infant had a 50 percent chance of receiving higher oxygen target saturation levels, and a 50 percent chance of

receiving lower levels. In the second arm, each infant had a 50 percent chance of receiving oxygen by CPAP and a 50 percent chance of receiving intubation with surfactant, a viscous substance that helps keep the lungs' air sacs open. Although surfactant normally is produced by the lung, premature infants are not ready to make surfactant at first and suffer from severe breathing difficulties.

Researchers Compare Higher Oxygen Levels To Lower Levels

Higher oxygen levels have been linked to an increase in the risk of retinopathy of prematurity (ROP), a condition affecting the retina. The current study was undertaken to determine if slightly reduced oxygen levels would allow infants to remain healthy while reducing their risk for ROP. Information on ROP is available from the National Eye Institute.

For the arm of the study that compared oxygen levels, the infants were assigned at random to receive oxygen at one of two levels. The lower level consisted of 85 to 89 percent oxygen saturation in the babies' blood; the higher level 91 to 95 percent. The infants also were assigned at random to receive oxygen either through a ventilator or a CPAP machine.

The researchers evaluated the infants at the two oxygen saturation levels in a single combined measure, referred to as the combined outcome of their survival and their likelihood of experiencing ROP. No overall difference emerged between the groups in terms of this measure. However, there was a striking difference when survival and likelihood of experiencing ROP were considered separately.

More of the infants on the low [oxygen level](#) died than did infants on the higher level: 19.9 percent compared to 16.2 percent. But among those

who survived, fewer on the lower level of oxygen developed ROP: 8.6 percent versus 17.9 percent in the higher-oxygen group.

"Many doctors believe that optimal oxygen saturation levels fall between 85 and 95 percent," Dr. Carlo said. "Our results offer much needed data on which to base treatment decisions."

CPAP Compared to Traditional Ventilator-Surfactant Therapy

A second arm of the study compared the standard ventilator treatment and surfactant for preterm respiratory distress to treatment with CPAP, which involves passing air through an infant's nose via prongs that rest in the nostrils. The standard ventilator treatment involves placing a breathing tube in a newborn's windpipe to provide oxygen and surfactant. It is not possible to deliver surfactant with CPAP.

In this arm of the study, newborns who were randomly assigned to the ventilator-surfactant treatment had a breathing tube placed in their windpipes within an hour of birth and received a dose of surfactant. Those who obtained CPAP treatment received oxygen through prongs placed in their nostrils, also within the first hour of life. Any infant receiving CPAP who subsequently did not achieve adequate oxygen levels in their blood was placed on a ventilator. Of the infants who received CPAP treatment initially, 83 percent required a ventilator tube in the windpipe and 67 percent received surfactant.

"Surfactant and intubation together have been shown to reduce the risk of serious complications and death in preterm infants," Dr. Finer said. "But the use of CPAP also grew during the last 10 or 15 years, without randomized studies to test it and compare it to surfactant."

The researchers looked at mortality and at a lung condition called bronchopulmonary dysplasia, which is characterized by a need for oxygen therapy when the baby is four weeks short of his or her original due date, or 36 weeks after the mother's last menstrual period. When researchers compared CPAP to surfactant on a combined measure of mortality and bronchopulmonary dysplasia, the two types of breathing therapy were practically identical.

"The study shows that CPAP is an effective alternative to surfactant in preterm infants," Dr. Higgins said. "Because it is less invasive than ventilator therapy, CPAP appears to be an appropriate first treatment for preterm newborns. If CPAP is unsuccessful, an infant can be placed on a ventilator and given surfactant."

By other measures, children initially placed on CPAP actually fared somewhat better than children who had received surfactant with the ventilator. They were more likely to have survived and to not require breathing therapy a week after being born. They were also less likely to need steroid treatment for their lungs; and they spent less time overall on ventilators.

Furthermore, the earliest [preterm infants](#) in the study, born at 24 to 25 weeks gestation, were less likely to die if they had received CPAP than if they had received surfactant as the initial treatment in the study.

The team will evaluate the children again when they are 18 to 22 months old, to learn whether any differences arise among the children who took part in the different treatments arms of the study.

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