

Strategy confirmed to help doctors determine when to treat retinopathy of prematurity

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Scientists have shown that through an eye exam, doctors can identify infants who are most likely to benefit from early treatment for a potentially blinding eye condition called retinopathy of prematurity (ROP), resulting in better vision for many children.

These long-term results of the Early Treatment for Retinopathy of Prematurity (ETROP) study confirm that the visual benefit of early treatment for selected infants continues through 6 years of age. The research, published April 12 online in *Archives of Ophthalmology*, was supported by the National Eye Institute (NEI), part of the National Institutes of Health.

"This study has set the standard of care for infants with ROP by showing that early treatment of selected high-risk premature babies has positive longer-term results on vision," said NEI Director Paul A. Sieving, M.D., Ph.D.

An estimated 15,000 premature infants born each year in the United States are affected by some degree of ROP. At-risk infants generally are born before 31 weeks of the mother's pregnancy and weigh 2.75 pounds or less.

This disease, which usually develops in both eyes, is one of the most common causes of <u>vision loss</u> in children. About 90 percent of infants with ROP have a mild form that does not require treatment, but those who have a more severe form can develop lifelong visual impairment,



and possibly blindness.

During pregnancy, the <u>blood vessels</u> of the eye gradually grow to supply oxygen and essential nutrients to the light-sensitive retina. If a baby is born prematurely, growth of the blood vessels may stop before they reach the edge of the retina. In these <u>newborns</u>, abnormal, fragile blood vessels and retinal tissue may develop at the edges of the normal tissue. The abnormal vessels can bleed, resulting in scars that pull on the retina. The main cause of <u>visual impairment</u> and blindness in ROP is retinal detachment. Laser therapy or cryotherapy, using freezing temperatures, are the most effective treatments to slow or stop the growth of abnormal blood vessels.

"The long-term study has given clinicians evidence that infants with ROP should be treated with different strategies based on an infant's risk for a severe form of the disease, which can be determined through an exam at the bedside," said study chair William V. Good, M.D., of Smith-Kettlewell Eye Research Institute in San Francisco.

Previously, doctors treated infants with ROP when they estimated their risk for retinal detachment to be 50 percent, a strategy developed through the NEI-supported Cryotherapy for Retinopathy of Prematurity study. Although this was a major finding, many infants still went on to develop severe eye disease. Therefore, the first phase of the ETROP study aimed to discover if doctors could identify infants at a higher risk for progression of the disease and intervene early to improve their vision.

In 2003, the ETROP study found that early treatment—upon diagnosis as higher risk for severe ROP—improved the vision and retinal health of certain infants after nine months. These infants had dilated or twisted blood vessels in the <u>retina</u> and substantial growth of new blood vessels, classified as Type 1 disease. Eyes with Type 2 ROP, or a more moderate



amount of new blood vessel growth, did not benefit from early treatment. Doctors could predict which infants were more likely to benefit from early treatment by identifying certain eye characteristics, such as the appearance and location of the blood vessels.

The current study followed the same 370 children through 6 years of age, when researchers checked their vision and examined the development of their eyes. The nine-month study recommendations were confirmed through 6 years. Type 1 eyes benefitted from early treatment, and Type 2 eyes had similar results with either early treatment or treatment at the standard time. Seventy-five percent of the early-treated Type 1 eyes were spared legal blindness, compared with 67 percent of Type 1 eyes that received treatment at the standard time. Of the Type 2 eyes that were carefully monitored for disease progression through the standard protocol, more than half improved without treatment.

"Unfortunately, not all eyes selected for early treatment do well," said Robert J. Hardy, Ph.D., director of the ETROP study coordinating center and professor of biostatistics at the University of Texas School of Public Health in Houston. "Additional research is needed to identify still better methods for the prevention and treatment of severe ROP."

Provided by NIH/National Eye Institute

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