

# eNeonatal Review

Jointly presented by the Johns Hopkins University School of Medicine and the Institute for Johns Hopkins Nursing

Supported by an educational grant from INO Therapeutics



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## NEWSLETTER

**This month eNeonatal Review is unveiling our new look as well as several exciting features that we'd like to announce:**

- Welcome our new program directors Mary Terhaar, RN from the Johns Hopkins School of Nursing and Robert J. Kopotic, MSN, RRT, FAARC of ConMed Corporation.
- Each issue now carries up to 1.0 CME/CE credits for Physicians and Nurses.
- Respiratory Therapists can use our [online tool](#) to determine how to satisfy their CE requirements using AMA PRA category 1 credits.
- Our [Ask The Authors](#) feature begins this month, allowing subscribers to submit questions on this issue's topic. Responses by the authors will appear in next month's edition.

## OCTOBER 2005 VOLUME 3, NUMBER 2

### In this issue...

Retinopathy of Prematurity (ROP) has, since its first description in 1942<sup>1</sup>, remained a major cause of visual impairment in premature infants. Advances in the screening, treatment, and follow-up of ROP have been counterbalanced by the advances in neonatology that have made increased survival for extremely premature infants possible. While our understanding of the pathogenesis of ROP at a cellular level has increased, definitive medical treatment of neoproliferative eye disease has not yet reached the bedside.

In this issue we review recent changes in the indications for diagnosing and treating ROP, the incidence of the condition around the world, the long-term effect of ablative treatment (cryotherapy or laser therapy) on visual function, and the evolving nomenclature that allows for a more effective description of the early stages of this disease in extremely low birth weight infants.

#### 1. Terry TL.

Extreme prematurity and fibroblastic overgrowth of persistent vascular sheath behind each crystalline lens: I. Preliminary report. Am J Ophthalmol 1942;25:203-204.

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### Course Directors

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### This Issue

- **Commentary** Our guest editor opinion
- **The Incidence Of ROP**
- **A Global Perspective Of ROP**
- **Long-Term Benefits Of Earlier Treatment**
- **Timing Of Cryotherapy**
- **ROP Staging Revisited**

### Learning Objectives

The Johns Hopkins University School of Medicine and The Institute for Johns Hopkins Nursing take responsibility for the content, quality, and scientific integrity of this CE activity.

**At the conclusion of this activity, participants should be able to:**

- Discuss the key factors regarding the incidence of Retinopathy of Prematurity (ROP) in the US and around the world.

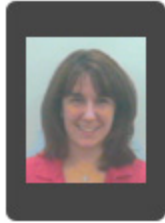
• **Ask the Author**

## Guest Editors of the Month



Commentary:  
**Michael X. Repka, MD**

Professor of Ophthalmology  
and Pediatrics  
Johns Hopkins University  
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Reviews:  
**Theodora A. Stavroudis, MD**

Johns Hopkins  
Neonatology Fellow  
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### Guest Faculty Disclosure

Michael Repka, MD  
Faculty Disclosure: No relationship with commercial supporters.

Theodora A. Stavroudis, MD  
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(ROP) in the US and around the world.

- Summarize the current research into the advantages/disadvantages of early treatment of the disease.
- Differentiate between the various classifications of ROP as redefined in 2005.

### Program Information

#### CE Info

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#### Length of Activity

1.0 hours

#### Expiration Date

October 18, 2007

#### Next Issue

November 15, 2005

## Commentary

Ablative therapy (cryotherapy and laser therapy), shown to be effective in reducing overall visual morbidity from ROP by the Cryotherapy for Retinopathy of Prematurity Cooperative Group, is imperfect. Thirty percent of treated eyes (1986-1988) showed an unfavorable visual outcome at 15 years. While some clinicians had hoped that continually improving nursery care would create a reduction in the incidence ROP, others have worried that the survival of ever-smaller infants would lead to an increased incidence. Data from the Early Treatment Study (1999-2001) found that the incidence of ROP remained exactly the same, although the mean birthweight of the affected children had dropped by almost 100 grams and the mean gestational age by nearly a week — suggesting that these two effects have balanced out in the United States. The visual outcome with early treatment has improved but nearly 15% of babies have severe visual impairment.

While the outcomes are better in the US and Europe, blindness from ROP in the former Eastern Bloc and in Latin America is of epidemic proportions. In these countries there is a shortage of both ophthalmologists trained to screen for the disease and of the equipment necessary for screening in those hospitals with NICUs. These shortages may foreshadow a problem in the developed world, with ophthalmologists being forced to forgo neonatal screening by fear of insurance claims. Without societal and legal intervention, such care may become only available from those few physicians in large centers who are covered by institutional insurance.

With the advent of ICROP, clinicians had a framework to describe ROP and define a threshold for treatment. While these definitions have served well for two decades, they do not describe the disease when it occurs in very premature patients today. Plus disease — defined by just two quadrants rather than four — is more common, and also compatible with the definitions used in clinical trials since 1990 and current practice. If the ophthalmologist describes Plus disease in the consultation report, the neonatologist should inquire about the timing of treatment, as there are only a few forms of ROP with Plus for which treatment is withheld.

The second change in ICROP classification is visible only with the indirect ophthalmoscope. Stage 3 was initially described as preretinal neovascularization and looked like a reddish orange sausage on the surface of the retina. This new form of Stage 3 (AP-ROP) is a network of fibrovascular proliferation on the surface of the

retina. If not recognized and treated quickly, the prognosis is very poor with rapid progression to detachment and loss of vision.

Because of the incomplete success achieved by ablative therapy, many clinicians in the 1990's began to treat prior to threshold. However, even with early treatment, more than 10% of affected children will be considered legally blind. It appears that further improvement in visual outcome, absent a reduction in the rate of prematurity in the developed world, will come by improving systems for screening, insuring that there are no missed exams, increasing frequency of exams, improving follow-up upon discharge from the nursery, more effectively informing parents of the need for adherence to the follow-up schedule, training more screeners and trained personnel to assure prompt availability of treatment, and continuing to improve the quality of the medical and surgical care delivered to these children from delivery to discharge.

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## THE INCIDENCE OF ROP

**Good WV, Hardy RJ, Dobson V, Palmer EA, Phelps DL, Quintos M, Tung B**

Early Treatment for Retinopathy of Prematurity Cooperative Group. The incidence and course of retinopathy of prematurity: findings from the early treatment for retinopathy of prematurity study. *Pediatrics*. 2005 Jul;116(1):15-23.

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### Follow-up data showing the incidence of the disease has remained unchanged in 15 years

Retinopathy of Prematurity (ROP) is an important cause of visual impairment in childhood, especially for infants born at less than 28 weeks' gestation and weighing less than 1250 grams. The incidence of ROP in 1986 and 1987 previously reported by the Cryotherapy for Retinopathy of Prematurity Cooperative (CRYO-ROP) Group had been 65.8% (infants <1250 grams). The Early Treatment for Retinopathy of Prematurity Cooperative Group (ETROP) examined 6998 infants at 26 centers throughout the United States weighing less than 1250 grams born from October 1, 2000, to September 30, 2002 and monitored 5541 infants for the development and progression of ROP. Their 2005 report found the incidence of ROP to be 68% with more Zone I ROP (9.1% vs. 2% in the CRYO-ROP Study) and more prethreshold ROP among infants (36.9% vs. 27.1% in the CRYO-ROP Study). The authors speculate that this is likely due to a higher proportion of low birth weight and low gestational age infants (740 vs. 831 g and 25.6 vs. 26.5 weeks) in the ETROP study, as well as to methodological differences such as more frequent exams of infants with Zone II Stage 2 or Zone I vessel development as compared to the CRYO-ROP Study. The incidence of ROP was 92.7% in infants with a birth weight of less than 750 grams and 89% for infants with a gestational age of less than or equal to 27 weeks. Onset of Stage 1 ROP disease was 34.1 weeks gestation compared to 35.1 weeks for Stage 2 and 36.6 weeks for Stage 3.

In summary, the ETROP Group found that the overall incidence of ROP in the US has remained unchanged despite advances in neonatal care. Moreover, the ETROP study confirmed that although the incidence of ROP is similar among white and black infants, prethreshold ROP occurs more commonly among white children. The reliable timing of ROP disease based on gestational age (independent of gestational age at birth) suggests that factors exist in fetal development which may predispose an infant to ROP.

## A GLOBAL PERSPECTIVE OF ROP

**Gilbert C, Fielder A, Gordillo L, Quinn G, Semiglia R, Visintin P, Zin A; International NO-ROP Group.**

Characteristics of infants with severe retinopathy of prematurity in countries with low, moderate, and high levels of development: implications for screening

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## Connecting the incidence of the disease to the level of technological development

The incidence of blindness as a result of ROP varies significantly between countries. These differences can be explained by the availability and quality of neonatal care, ROP screening protocols, and availability of treatment centers. In developed countries, the impact of recent advances in neonatal care is evidenced by the fact that the population of infants affected with ROP has changed — from involving more mature infants in the 1940s and 1950s to being primarily a disease of extremely premature infants in the present day. However, in the moderately developed countries in Latin America and of the former Soviet Union, ROP has emerged as a major cause of blindness; similarly, two-thirds of the 50,000 pediatric cases of blindness secondary to ROP are estimated to be in South America. In contrast, blindness from ROP is rare in poorly developed countries where survival rates of premature infants are low. In an attempt to add insight into populations of infants at risk for ROP, ascertain appropriate ROP screening criterion for global populations of infants, and compare the incidence of ROP worldwide, Gilbert et al. queried ophthalmologists in 40 countries.

The study found that the birth weights of ROP patients in three highly developed countries were less than 800 grams compared to greater than 1,000 grams in moderately and poorly developed countries (exceptions were Chile and Brazil). The mean gestational ages of affected infants in highly developed countries were less than 26 weeks compared to a gestational age range in less developed countries of 26.3 weeks (Lithuania) to 33.5 weeks (Ecuador). Thirteen percent of the infants with severe ROP from moderately and poorly developed countries had birth weights of more than 1500 grams and gestational ages of more than 32 weeks, factors which would have excluded them from screening based on the recommendations by the Royal College of Ophthalmologists. This compares to only 1 (0.4%) of 262 infants who was treated for threshold disease in a highly developed country that exceeded United Kingdom screening criteria. Although this study has several methodological weaknesses, it represents an excellent international snapshot of the incidence of ROP.

The observation that bigger, more mature infants develop severe ROP or present too late for effective treatment in developing countries has led to the modification of screening criteria in some countries of Latin America to include larger (<2000 g) and more mature (<37 weeks) infants. However, expanding the screening criteria in resource-poor countries has led to concerns about placing additional burdens on the health care system. Nevertheless, this study further emphasizes the need to consider criteria such as the availability of skilled personnel, financial resources, and availability of advanced neonatal centers and ROP treatment centers when formulating screening guidelines for different countries.

## LONG-TERM BENEFITS OF EARLIER TREATMENT

Palmer EA, Hardy RJ, Dobson V, Phelps DL, Quinn GE, Summers CG, Krom CP, Tung B; Cryotherapy for Retinopathy of Prematurity Cooperative Group.

15-year outcomes following threshold retinopathy of prematurity: final results from the multicenter trial of cryotherapy for retinopathy of prematurity. Arch Ophthalmol. 2005 Mar;123(3):311-8.

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## Gaining insight into the sequelae of early diagnosis and treatment

Cryotherapy has been considered the standard of care for threshold ROP since 1988 when the Cryotherapy for Retinopathy of Prematurity (CRYO-ROP) Study revealed the reduction of unfavorable retinal outcomes after the application of transscleral cryotherapy to the avascular retina when threshold disease was reached. Long-term follow-up for ROP to date has been based on clinical judgment. In order to gain more knowledge about the long-term benefits of early treatment and the sequelae of severe ROP, the CRYO-ROP group conducted a 15-year follow-up study to report the incidence of retinal detachment as well as other ocular structure and visual acuity outcomes.

Of the 291 infants that were enrolled in the original study, 198 were eligible and available for follow-up, which found that 30% of treated eyes had unfavorable structural outcomes (partial or total retinal detachment, cataract, retrolental membrane or enucleation) at 15 years of age as compared to 51.9% of control eyes. In addition, the incidence of blindness was reduced from 55.1% in control eyes to 36.3% in treated eyes. The study also found that there was a gradual increase in unfavorable structural outcomes between the 1-year and 15-year examinations, and that new retinal detachments were observed in both treatment and control eyes despite normal or nearly normal posterior poles and macular ectopia without folding at the 10-year examination. This finding highlights the importance of continued long-term follow-up in patients with a history of severe ROP.

Furthermore, the study reports a 30% decrease in unfavorable visual acuity outcomes (defined as equal to or worse than 20/200) in eyes that had been treated as compared with control eyes at 15 years of age. The visual acuity of treated eyes remained stable between the 10- and 15-year examinations (0.06% per year increase in unfavorable outcome), while that of control eyes averaged a 0.44% per year increase in unfavorable outcome. Finally, thirty eyes had visual acuity of 20/20 or better at the 15-year examination — thus revealing that normal adult vision is possible following severe ROP.

## TIMING OF CRYOTHERAPY

### Early Treatment For Retinopathy Of Prematurity Cooperative Group

Revised indications for the treatment of retinopathy of prematurity: results of the early treatment for retinopathy of prematurity randomized trial. Arch Ophthalmol. 2003 Dec;121(12):1684-94.

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### Defining treatment selection criteria.

There has been much debate about the timing of cryotherapy, with some practitioners advocating earlier intervention to help prevent poor outcome and others raising concerns of unnecessary surgical intervention for eyes that would regress spontaneously. In an effort to develop treatment selection criteria to more effectively identify those who are at highest risk for developing threshold ROP and thus would likely benefit from earlier intervention, the Early Treatment for Retinopathy of Prematurity Cooperative (ETROP) Group enrolled 828 infants at 26 clinical sites in a randomized prospective clinical trial that initiated ablative therapy (laser therapy or cryotherapy) within 48 hours of an infant receiving the first diagnosis of high-risk prethreshold ROP. Eyes were considered high-risk prethreshold when they were determined to have a 15% or greater risk of developing threshold ROP by the RM-ROP2 model.

Of the 828 infants enrolled in the study, 499 infants were classified as high-risk for developing threshold ROP, although 401 of those infants were enrolled in the randomized trial due to methodological reasons. The mean birth weight was 703 grams and the mean gestational age was 25.3 weeks with a mean post-menstrual age of 35.2 +/- 2.3 weeks at the time of prethreshold treatment. The largest category of high-risk prethreshold ROP was for eyes with Zone II, Stage 3 and Plus disease (42.1% of treated eyes, 43.7% of control eyes) followed by Zone I, Stage 1 or 2 and no Plus disease (27.4% of treated eyes, 26.1% of control eyes).

The study found that unfavorable visual acuity outcomes (<1.85 cycles per degree on grating acuity) were reduced from 19.5% to 14.5% and unfavorable structural outcomes were reduced from 15.6% to 9.1% at 9 months of follow-up in treated eyes. However, the greater benefit occurred for those eyes with a 30% or greater risk for developing threshold ROP by the RM-ROP2 model and to those eyes who had Zone I, Stage 3 ROP with or without Plus disease. Moreover, only 1.3% of those infants who were diagnosed with low-risk prethreshold eyes (<15% risk of unfavorable outcome by RM -ROP2) had unfavorable outcomes.

The research group suggested that peripheral retinal ablation should be considered for any eye with Type 1 ROP (defined as Zone I with Plus disease, Zone I, Stage 3 disease and Zone II Stage 2 or 3 with Plus disease). In addition, continued serial examinations should be considered for Type 2 ROP (defined as Zone I, Stage 1 or 2 without Plus disease, or Zone II, Stage 3 without Plus disease).

### International Committee for the Classification of Retinopathy of Prematurity.

The International Classification of Retinopathy of Prematurity revisited. Arch Ophthalmol. 2005 Jul;123(7):991-9.

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### Changes in nomenclature to define a more aggressive form of ROP and Pre-Plus disease

The International Classification of Retinopathy of Prematurity (ICROP) was established in 1984 and 1987 to aid in the understanding of ROP, help identify populations of infants at risk, establish screening criteria, and institute clinical treatment trials and protocols. These guidelines were further revised in 2005 to include a more virulent form of ROP observed in the smallest infants (Aggressive Posterior ROP) and describe an intermediate level of Plus disease (Pre-Plus).

ROP is graded by stages of abnormal vascular development and retinal detachment, zones of disease, and extent of retinal involvement. The stages and zones of ROP have remained unchanged in the 2005 ICROP revision and are summarized in the table below:

Stage	Description
<b>I</b>	<b>Demarcation line</b> - structure that separates the avascular retina anteriorly from the vascularized retina posteriorly
<b>II</b>	<b>Ridge</b> - arises in the region of the demarcation line; extends above the plane of the retina; may have small, isolated tufts of neovascular tissue known as "popcorn"
<b>III</b>	<b>Extraretinal Fibrovascular Proliferation</b> - extends from the ridge into the vitreous; subdivided into mild, moderate, and severe
<b>IV</b>	<b>Partial Retinal Detachment</b> - subdivided into extrafoveal (4A) and foveal (4B); most are concave and circumferentially oriented
<b>V</b>	<b>Total Retinal Detachment</b> - usually funnel shaped; stage is subdivided into anterior and posterior parts.

The definition of Plus Disease has been refined. The diagnosis is made when sufficient vascular dilatation and tortuosity are present in at least 2 quadrants of the eye, and a "+" signal is added to the Stage number to designate the presence of Plus disease.

Also new to the 2005 revision of the ICROP is the addition of Pre-Plus disease. By definition, it represents vascular abnormalities of the posterior pole that are insufficient for the diagnosis of Plus disease, but demonstrate more arterial tortuosity and more venous dilatation than normal. Pre-Plus disease is also to be noted beside the stage number of ROP.

In addition, Aggressive Posterior ROP (AP-ROP) has been added to the ICROP. It is defined as an uncommon, rapidly progressive form of ROP that if left untreated progresses to Stage 5 ROP. It is characterized by its posterior location and prominence of Plus disease, and its diagnosis can be made on a single visit. It is usually observed in Zone I or in the posterior Zone II.

With the new revisions made to the ICROP, better descriptions of the disease state now exist to help facilitate discussion among the medical community, caregivers, and parents in regards to understanding and managing this disease.

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### Ask the Author

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## The eNeonatal Review Team asked the October faculty a few questions

**Q** Infants are often treated for ROP back to the referring hospital. What are the legal obligations regarding exams and assuring that they are done in the accepting hospital?

**A** The answer to this question varies with the location of your practice and the local standard of care. Thus for legal advice, I recommend that you consult with your institutions' legal and risk management teams and malpractice carrier.

However in my personal opinion your duty is to inquire whether timely exams are available in the accepting hospital before sending the infant.

Further, good communication between the two neonatology care teams is critical to assure adequate follow-up. It includes documentation of the ROP status and the recommended date for the next exam.

**Q** What are the current recommendations for oxygen saturation levels to reduce the likelihood of ROP? How do these recommendations change as infants get older?

**A** Currently there are no published guidelines on the appropriate oxygen saturation levels for premature infants. A 2001 Cochrane review showed that unrestricted, unmonitored oxygen therapy has potential harms, without clear benefits. Restriction of oxygen significantly reduced the incidence and severity of retinopathy of prematurity without unduly increasing death rates. However, it remains unclear what the optimal target range for maintaining blood oxygen levels in preterm/LBW infants is. For further information, see:

Askie LM, Henderson-Smart DJ. [Restricted versus liberal oxygen exposure for preventing morbidity and mortality in preterm or low birth weight infants.](#) Cochrane Database Syst Rev. 2001;(4):CD001077.

and

Askie LM, Henderson-Smart DJ, Irwig L, Simpson JM. [Oxygen-saturation targets and outcomes in extremely preterm infants.](#) N Engl J Med. 2003 Sep 4;349(10):959-67.

**Q** What are the pros and cons for tele-medicine (retinal cam) in regards to neonatal eye exams?

**A** The validity of tele-medicine — with retinal photographs as a substitute for the serial clinical examinations — remains to be proven via an adequately powered comparison trial. Such a trial would need to specifically address the probability of false negatives and the magnitude of over-referral. In places where there is a shortage of examiners this may be an important alternative; however, an excellent photographer is indispensable and would raise the cost of providing this service. In terms of pros, this test could be widely available once trained personnel were in place to provide the service. The cons are largely the cost of the instrument and the uncertainty about the comparability of findings to the clinical examination. Some studies have shown the instrument to be more sensitive to disease severity compared to the ophthalmoscopic exam, which would likely mean more children would get treated, since the treatment thresholds are based on our experience with the ophthalmoscopic examination of the retina.

### Accreditation · [back to top](#) Physicians & Nurses

This activity has been planned and implemented in accordance with the Essential Areas and policies of the Accreditation Council for Continuing Medical Education through the joint sponsorship of The Johns Hopkins University School of Medicine and The Institute for Johns Hopkins Nursing. The Johns Hopkins University School of Medicine is accredited by the ACCME to provide continuing medical education for physicians.

### Respiratory Therapists

Respiratory Therapists should [click here](#) to confirm that AMA PRA category 1 credit is accepted toward fulfillment of RT

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### **Target Audience · [back to top](#)**

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- Differentiate between the various classifications of ROP as redefined in 2005.

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- Dr. Noguee has indicated a financial relationship of grant/research support with Forest Laboratories and has received an honorarium from Forest Laboratories.
- Dr. Lawson has indicated a financial relationship of grant/research support from the NIH. He also receives financial/material support from Nature Publishing Group as the Editor of the Journal of Perinatology.
- Dr. Lehmann has indicated a financial relationship with Eclipsys Corporation.

All other faculty have indicated that they have not received financial support for consultation, research, or evaluation, nor have financial interests relevant to this e-Newsletter.

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