Early Treatment ROP Study: How It Affects My Practice

Michael T Trese MD

I. Introduction

The Early Treatment ROP (ETROP) Study concluded that early treatment can improve outcomes. See Table 1.

II. Results at 9 Months

Reduced unfavorable outcomes from:

A. Unfavorable grating visual acuity outcomes of 19.5% (CRYO-ROP Study Criteria) to 14.5% (ETROP Study Criteria)

B. Unfavorable structural outcomes of 15.6% (CRYO-ROP Criteria) to 9.1% (ETROP Criteria)

III. Flaws in ETROP Study

A. Recognition of flat neovascularization

B. Lack of standardization of treatment protocol

C. Zone 1 definition

D. Laser and cryo allowed

IV. Changes From CRYO-ROP Criteria

A. Treat at 48 hours

B. Need to be available for half week examining

V. Treatment of Vascularly Active Eyes

The ETROP Study advises the examiner to consider treatment for Type 1 ROP. In reality, not treating could leave the baby and doctor in a poor position.

ETROP encourages treatment of vascularly active eyes and eyes with zone I disease. Zone I is poorly defined. (1 clock hour of juncture of avascular and avascularized retina with zone I is a zone I eye. This eye behaves like a zone II eye.)

Lower failure rates are achieved with treatment of vascularly active eyes.

VI. ROP of the 21st Century

The appearance of zone I eyes has changed as smaller babies are kept alive, and the need to be aware of the appearance of flat neovascularization in zone I is important. The shunt in zone I is often without ridge tissue.

Flat neovascularization lies anterior to the shunt vessels, which can be seen at multiple sites posterior to the neovascularization.

Typical stages 1 and 2 are not seen in eyes where 10–12 clock hours of vessels are in zone I. In addition, stage 3 (flat neovascularization) in zone I rarely if ever appears without plus disease.

VII. Treatment Pattern

The treatment pattern we use is a spot separated by half a space in all but the horizontal meridians, and for these we use a separation of a full space to reduce damage to these by posterior ciliary vessels.

Table 1. ETROP Treatment Criteria Table

Consider Treatment – Type 1	Zone I Any Stage ROP with plus
	Zone I Stage 3 ROP with or without plus
	Zone II Stage 2 or 3 with plus
Watch – Type 2	Zone I Stage 1 or 2 ROP without plus
	Zone II Stage 3 ROP without plus

Must distinguish flat stage 3 in Zone I as it is treated with or without plus.

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PhotoROP Study: Solution to ROP Screening Crisis

Protecting Infants From Poor Outcome and Ourselves From Malpractice Risk

Antonio Capone Jr MD for the Photo-ROP Study Group

I. ROP Management Challenges
   A. Manpower
   B. Experience
   C. Medicolegal

II. Manpower
   A. Location
   B. Workload
      1. Impact of the ETROP
      2. Exams / NICU visits per week / lasers

III. Experience
   A. Improved survival of the extremely premature
   B. Geographic diversity of level II/III NICUs
   C. Impact on the ophthalmic community

IV. Medicolegal
   A. Relatively infrequent suits, but...
   B. Medicolegal exposure
      1. Common
         a. Failure to diagnose
         b. Delay in referral
         c. Lost to follow-up
      2. Rare: Poor outcome after timely laser / surgery
      3. Greatest vulnerability – screening
      4. Does this serve infants / society well? Underscores weak links in ROP care

V. PhotoROP
   A. Purpose: To evaluate the use of remote digital retinal photographs in the diagnosis of clinically significant ROP in longitudinally screened high-risk infants.
   B. Study design: Prospective, longitudinal cohort study
   C. PhotoROP clinical centers
      1. William Beaumont Hospital, Royal Oak: Antonio Capone Jr
      2. Study Headquarters: Michael T Trese
      3. The Western Eye Hospital, London: Alistair R Fielder
      4. Louisiana State University, Baton Rouge: ME Hartnett
      5. UCLA Jules Stein Institute, Los Angeles: Steven Schwartz, Christine Gonzales
      6. Alberta Children's Hospital, Calgary: Anna Ells
      7. National Children's Hospital, Dublin: Michael O'Keefe
      8. Emory University, Atlanta: G Baker Hubbard
   D. Entry criteria
      1. Birth < 31 weeks PCA
      2. Birth weight < 1000 grams
      3. 66% ROP incidence < 1251 gm BW (CRYO-ROP)
      4. Enrolled 62 consecutive infants
   E. Methods: All infants were examined longitudinally
      1. Indirect ophthalmoscopy
      2. Digital photography
      3. Images read remotely by masked readers
   F. Prior studies
      1. Feasibility
      2. Sensitivity or specificity, all stages of ROP
      3. Timing of a single RetCam examination
      4. Schwartz SD, Harrison SA, Ferrone PJ, Trese MT. *Ophthalmology* 2000;107:25-28.
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      6. Yen KG, Hess D, Burke B, et al. *J AAPOS.* 2002;6:64-70.
   G. A pragmatic approach for identifying referral-grade ROP
      1.Clinically significant ROP (CSROP)
      2. Zone 1 ROP
      3. Plus disease
      4. Any stage 3 ROP

H. Results
   1. Enrolled: 62 infants (124 eyes)
   2. Excluded: Single examination, 5 infants (10 eyes)
   3. Study sample: 57 infants (114 eyes)
   4. Birth weight:
      a. Range: 440–1675 grams
      b. Mean: 843 grams
   5. Postmenstrual age
      a. Birth: 23–31.4 weeks (mean 26.6)
      b. First exam: 32.5 weeks (mean)
   6. Target: weekly exams
   7. Missed exams (instability, etc.): 73
   8. Examinations (image sets): 325
   9. Excluded image sets: 10 (3%)
   10. Once an eye received laser further examinations were excluded.

I. Study sample
   1. 315 exams
   2. Interpretable: 293 (93%). All with interpretable image sets within 2 weeks
      a. Small pupil
      b. Dark fundus
      c. Vitreous haze
      d. Inadequate visualization
      e. Race

J. Follow-up (weeks)
   1. Mean: 5.32
   2. Median: 9.00
   3. Longest in prior studies = 4.0

K. Statistical analyses
   1. Disease positive (D+): CSROP by I.O.
   2. Test positive (T+): CSROP by images
   3. Sensitivity: D+/T+
   4. Specificity: D-/T-
   5. Positive predictive value: T+/D+
   6. Negative predictive value: T-/D-

L. CSROP: 33% (37/114 eyes)
   1. Sensitivity: 100%
   2. Specificity: 97%

M. Timing of diagnosis: CSROP was diagnosed by the Reading Center from 1–2 weeks earlier than by indirect ophthalmoscopy.

N. Minimum image necessary
   1. Clear media
   2. Single fundus image often adequate
   3. Challenging image sets
   4. Full complement of images necessary

VI. Conclusion

Longitudinal digital imaging is sensitive and specific for detection of CSROP.

VII. Discussion
   A. Formal cost-effectiveness studies of interest.
   B. High utility values for effectively managed ROP.
   C. Telemedicine strategies likely cost-effective.
   D. How do we protect the infants from poor outcomes and ourselves from malpractice risk?

VIII. ROP Management Challenges
   A. Manpower: All at-risk infants reliably screened
   B. Experience: Accurately staged
   C. Medicolegal: Paradigm that minimizes risk

IX. Streamlined ROP Screening
   A. Manpower: Digital fundus imaging of at risk infants weekly
   B. Experience: Centralized interpretation
   C. Medicolegal: Nationally standardized protocol with established performance standards

Adult-Onset Problems With ROP

William Tasman MD, Bradley T Smith MD

I. Introduction

Information in this presentation is based on a retrospective chart review of 47 patients (86 eyes) between 45 and 55 years of age who have ROP. Since the patients are 45 years or older we do not have information about their retinal status during the active phase of the disease. Cryotherapy and laser treatment were not in use when these patients were born, and percentages relate only to this selected patient population.

II. Demographics

A. Gender

1. Male: 33 (70.2%)
2. Female: 14 (29.8%)

B. Age in years (44 patients)

1. Range: 45–55 years
2. Mean: 49.8 years

C. Birth weight

1. Range: 794–1701 gm
2. Mean: 1251 gm

D. Gestational age

1. Range: 26–36 weeks
2. Mean: 30 weeks

III. Results

A. Posterior segment findings

1. Retinal dragging: 29/86 eyes (33.7%), most commonly noted retinal change. Dragging is temporal 80% of the time.
2. Retinal fold: 6/86 eyes (7%)

B. Retinal pigmentation posterior pole: 5/86 eyes (5.8%)

C. Rhegmatogenous retinal detachment (RRD)

1. RRD: 20/86 eyes (23.3%)
2. Reattached: 17/20 eyes (85%)

D. Retinal tears

1. Seven of 86 eyes developed symptomatic retinal tears (12.3%)
2. Treatment
   a. Cryo: 5
   b. Laser: 2

E. Exudative RD: 9 of 86 eyes (10.5%)

F. Cataract extraction

1. No cataract surgery: 29/86 eyes (33.7%)
2. Cataract surgery 1 or both eyes: 57/86 eyes (66.3%)
3. Nuclear sclerosis most common lens opacity, but posterior subcapsular cataracts also occur.

G. Cataract extraction

1. No cataract surgery: 8/47 patients (17%)
2. Cataract extraction 1 or both eyes: 39/47 patients (83%)
3. Fifty 50-year-old patients who were full term at birth were selected at random. Five of the 50 patients (10%) had undergone cataract surgery on 1 or both eyes, but 1 of the 5 had familial exudative vitreoretinopathy and another had Stickler syndrome.
4. Postoperative capsular phimosis and capsular opacification frequently occurs early, sometimes within 4–6 weeks of operation. Silicone IOLs are not recommended.
5. Postcataract visual results
   a. 20/30 or better: 12
   b. 20/30–20/60: 8
   c. Together, a. and b. = 20 (48%)
   d. 20/60–20/100: 4
   e. 20/100–20/400: 5
   f. CF: 7
   g. HM: 3
   h. LP: 3

H. Glaucoma

1. Glaucoma occurred in 4/86 eyes (4.7%)
2. Angle closure glaucoma: 2 eyes
3. Neovascular glaucoma: 2 eyes

I. Refractive errors: Information was available on 23 patients

1. Myopia was present in 16 of 23 patients (61.5%)
   a. Range: –0.50 D to –22.00 D
   b. Mean: –5.00 D

2. Overall incidence for myopia in the U.S. is about 20%

J. Visual acuity: Information was available for 84 eyes

1. 20/20–20/30: 23 (27.4%)
2. 20/30–20/60: 12 (14.3%)
3. 1. + 2. = 45 (41.7%)
4. 20/60–20/400: 18 (21.4%)
5. HM – CF: 20 (23.8%)
6. LP: 4 (4.8%)
7. NLP: 7 (8.3)

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Legal Issues in ROP

Dwain Fuller MD JD

Very low birth weight infants (birth weight less than 1500 gm) with visual loss from retinopathy of prematurity (ROP) have provided a fertile ground for plaintiffs' attorneys seeking large judgments. "Bad babies" as a class routinely result in huge awards against obstetricians. Ophthalmologists who examine and treat premature babies may soon join OBs on the endangered species list. In a number of communities in this country the pool of eye MDs willing to provide neonatal intensive care unit screening of babies has drastically shrunk. Many hospitals now find themselves paying significant monthly retainers to the remaining ophthalmologists who are willing to see such infants.

The most common legal action against pediatric ophthalmologists is related to care of infants with ROP, and ophthalmologists who see premature babies are particularly vulnerable to lawsuits. The unpredictability of the course of ROP makes proper treatment uncertain despite a multitude of published studies. In the U.S. approximately 600 low birth weight babies each year develop complete loss of sight or major visual loss. There exists the presumption that any baby who is blind or partially sighted from ROP has been damaged by improper medical care. This public bias exists despite the fact that salvage of some neonates as young as 22 weeks gestation age is now possible.

The cards are clearly stacked against any ophthalmologist who goes to court to defend him or herself against medical malpractice charges for management of ROP. Presenting a blind baby to a jury is guaranteed to elicit an outpouring of sympathy even if the ophthalmic care of the child was exemplary. Also, it will prove virtually impossible to educate a lay jury about the complexities of the treatment of eye problems of very low birth weight infants. Since blindness is a lifelong handicap, juries tend to make major awards to such plaintiffs. A further major risk to ophthalmologists who see neonates is that fact that they remain vulnerable to medical malpractice lawsuits for many years after their care of the infant. Most states have a statute of limitations of age 18 plus 2 added years; thus, the ophthalmologist routinely incurs a 20-year risk for each neonatal patient he or she evaluates.

Once an ophthalmologist has been sued for malpractice regarding the care of a ROP baby, there may be a strong, immediate incentive to cease to care for such babies. The fear is that were the ophthalmologist to lose the initial suit and later be sued for a similar ROP problem, the plaintiff's attorney would almost certainly try to invoke a charge of gross negligence against the ophthalmologist as a repeat offender. This might open the door for punitive damages that would not be covered by the doctor's malpractice insurance. Thus, a second successful lawsuit could bankrupt the unfortunate physician. Also, there is anecdotal evidence that a physician who is sued is at increased risk for a second suit during the next 18 months.

The secret for minimizing the legal risk for ophthalmologists who screen NICU babies and provide interventional treatment for ROP is meticulous record keeping, clear lines of responsibility for initiating screening and follow-up examinations, and excellent communication with the parents of such children. The request for initial screening should come from the NICU personnel. Once screening is accomplished and the follow-up examination(s) scheduled, the parents should be fully educated about the vital importance of continued care to avoid blindness and should sign documents to that effect. The Ophthalmic Mutual Insurance Company Web site provides just such a critical document.[1]

Courts have placed an inordinate burden on screening ophthalmologists to make certain that follow-up care does in fact occur for infants at risk. Although driving to the infant's home and dragging the child and his parents to the doctor's office is not mandatory, some juries seem to think that the ophthalmologist's responsibility is only slightly short of this.

The multi-billion dollar medical malpractice industry remains alive and well in this country despite modest steps of implementing tort reform in a handful of states. Tort reform at the national level continues to fail in Congress due to repeated blockage in the Senate by a contingent of senators friendly to trial lawyers. If the next vice president of this country turns out to be a trial lawyer who made his fortune suing doctors and hospitals, we can all kiss national tort reform good-bye for many a year.

Almost two-thirds of physicians in this country have been sued at least once. Ophthalmic Mutual Insurance Company data has shown that there is a cumulative 8% risk each year that any ophthalmologist in this country will be sued. Being an ophthalmologist who examines premature babies puts a doctor in a particularly vulnerable position.

In summary, the screening and treatment of the eyes of very low birth weight infants is of vital importance. But ophthalmologists who take on this responsibility might be well advised to look into personal asset protection plans long before a suit arrives on their desk. They may also wish to negotiate a substantial retainer from the hospitals they serve, as well as the possibility of being included under the liability umbrella insurance of the institution.

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