

Early Treatment for Retinopathy of Prematurity (ETROP) Study - 2003



Objective

To determine whether early ablation of avascular retina in high-risk "prethreshold" retinopathy of prematurity (ROP) improves visual acuity and structural outcomes compared to conventional management.

Methods

Design: Multi-center prospective RCT

Sample Size: n=401 eyes

Study Criteria:

1) Prethreshold ROP:

- Zone I, any stage less than threshold
- Zone II, any stage less than threshold

Threshold = Zone I or II, stage 3 with plus disease (<5 contiguous or 8 cumulative clock hours)

2) High-risk: >15% risk of blindness using RM-ROP2 model

Treatment Groups:

- Control (n=357)
- Early treatment within 48 hours using laser or cryotherapy (n=361)

Outcome Measures:

- Grating/visual acuity (9month/6year)
- Unfavorable retinal structural outcomes

Results

Point 1: Overall, there was significant benefit for treatment of eyes with high-risk prethreshold ROP at 9 months of age.

- Unfavorable visual outcomes were reduced from 19.5% to 14.5% (P = 0.01)
- Unfavorable structural outcomes were reduced from 15.6% to 9.1% (P < 0.001)

Point 2: Further subgroup analysis resulted in a new clinical algorithm for prethreshold disease:

- "Type 1" ROP = treat immediately
 - Zone I, any stage ROP with plus disease
 - Zone I, stage 3 ROP without plus disease
 - Zone II, stage 2 or 3 with plus disease
- "Type 2" ROP = cautious observation (52% of eyes will regress)
 - Zone I, stage I or 2 ROP without plus disease
 - Zone II, stage 3 ROP without plus disease

Point 3: At 6 years of age, the structural benefits of early treatment persisted for high-risk prethreshold ROP; however, visual acuity benefits were only present for eyes with type 1 ROP.

TLDR: Early peripheral retinal ablation improves structural and visual outcomes for eyes with type 1 ROP. Eyes with type 2 ROP should be managed with close observation.