Grating Visual Acuity Results in the Early Treatment for Retinopathy of Prematurity Study

The Early Treatment for Retinopathy of Prematurity Cooperative Group*

Objective: To compare grating (resolution) visual acuity at 6 years of age in eyes that received early treatment (ET) for high-risk prethreshold retinopathy of prematurity (ROP) with that in eyes that underwent conventional management (CM).

Methods: In a randomized clinical trial, infants with bilateral, high-risk prethreshold ROP (n = 317) had one eye undergo ET and the other eye undergo CM, with treatment only if ROP progressed to threshold severity. For asymmetric cases (n = 84), the high-risk prethreshold eye was randomized to ET or CM.

Main Outcome Measure: Grating visual acuity measured at 6 years of age by masked testers using Teller acuity cards.

Results: Monocular grating acuity results were obtained from 317 of 370 surviving children (85.6%). Analysis of grating acuity results for all study participants with high-risk prethreshold ROP showed no statistically significant overall benefit of ET (18.1% vs 22.8% unfavorable outcomes; P = .08). When the 6-year grating acuity results were analyzed according to a clinical algorithm (high-risk types 1 and 2 prethreshold ROP), a benefit was seen in type 1 eyes (16.4% vs 25.2%; P = .004) undergoing ET, but not in type 2 eyes (21.3% vs 15.9%; P = .29).

Conclusion: Early treatment of eyes with type 1 ROP improves grating acuity outcomes, but ET for eyes with type 2 ROP does not.

Application to Clinical Medicine: Type 1 eyes should be treated early; however, based on acuity results at 6 years of age, type 2 eyes should be cautiously monitored for progression to type 1 ROP.

Trial Registration: clinicaltrials.gov Identifier: NCT00027222


Methods

STUDY PARTICIPANTS

From October 1, 2000, through September 30, 2002, 401 infants developed high-risk prethreshold ROP and entered the randomized trial. Entry into the study was based on the presence of prethreshold ROP and a risk of blindness of greater than or equal to 15% (high risk).
to calculate whether an infant had high-risk ROP to CM, with treatment if ROP reached threshold severity. If high-risk prethreshold ROP (at high-risk prethreshold ROP) and the other eye in both eyes of 317 infants; these infants had one eye randomized to ET of the design of the ETROP Study.

- Low-risk prethreshold ROP
  - Zone I: Stage 1 any stage
  - Zone II: Stage 2 with plus disease
  - Stage 3 without plus disease
  - Stage 3 with plus, but less than threshold ROP

- Threshold ROP
  - Zone I: Stage 3 in 5 contiguous or 8 total sectors with plus disease
  - Zone II: Stage 3 in 5 contiguous or 8 total sectors with plus disease

- Type 1 ROP
  - Zone I: Any stage ROP with plus disease
  - Stage 3 without plus disease
  - Stage 3 with plus disease

- Type 2 ROP
  - Zone I: Stage 1 or 2 without plus disease
  - Stage 3 without plus disease

Abbreviations: RM, risk model; ROP, retinopathy of prematurity.

Indicates an RM developed from an analysis of data from the Cryotherapy for Retinopathy of Prematurity Study.

as determined by a risk model (RM-ROP2) that was developed from an analysis of data from the Cryotherapy for Retinopathy of Prematurity Study. High-risk prethreshold ROP was noted in both eyes of 317 infants; these infants had one eye randomized to ET (at high-risk prethreshold ROP) and the other eye to CM, with treatment if ROP reached threshold severity. If high-risk prethreshold ROP developed in only 1 eye and the fellow eye had less than severe or no ROP, the high-risk eye was randomized to ET or to CM. This occurred in 84 infants. Details of the design of the ETROP Study and details of the model used to calculate whether an infant had high-risk ROP have been published elsewhere.

Study protocols were approved by the review boards of all participating institutions, and parents provided written informed consent for participation in the extended follow-up study to allow vision measurements through 6 years of age.

ASSESSMENT OF GRATING ACUITY

A tester who was masked to the treatment history and ocular status of each eye assessed each child’s monocular grating acuity with the Teller acuity card procedure (Teller Acuity Cards II; Stereo Optical Company, Inc, Chicago, Illinois). The luminance of the cards was at least 10 candelas per square meter. Test distance was 84 cm but could be reduced to 55, 38, 19, or 9.5 cm for a child with low visual acuity. Testing was usually conducted with a Teller acuity card stage (Vistech Consultants, Inc, Dayton, Ohio), which provided a uniform field in which to display the cards. However, the stage was not used with children who had poor vision, for whom a close test distance was needed, or with children who had nystagmus, for whom the tester used vertical presentation of the cards to allow vision measurements through 6 years of age.

- Type 1 ROP
  - Stage 3 with plus disease
  - Stage 3 without plus disease

Figure 1. Algorithm (flowchart) for randomized infants. "Data were incomplete because of failure to cooperate with monocular testing or failure to have had amblyopia therapy prescribed.

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- Type 1 ROP
  - Stage 3 with plus disease
  - Stage 3 without plus disease

Data were included only if treatment for any amblyopia (judged by the examining ophthalmologist) had been prescribed for at least 4 weeks before the acuity test and if refractive error (measured by cycloplegic retinoscopy) had been

low easier detection of the grating lines. The right eye was tested first, followed by the left eye. All eyes were tested with corrective lenses prescribed to meet study protocol criteria. Assessment of grating acuity was performed before cycloplegia.

The tester, who was masked to the location of the grating on each card, showed the acuity cards sequentially, starting with a card containing a coarse (2.4 cycles/cm) grating. The tester used the child’s eye and head movements and/or the child’s pointing behavior in response to repeated presentations of each card to decide whether the child could discriminate the location of the grating on the card. If the child did not give evidence of seeing the initial grating, the tester continued testing with a card containing a coarser grating. The tester proceeded to cards containing finer and finer gratings until the child no longer gave evidence of being able to resolve the grating. Based on the child’s responses, the tester determined the highest spatial frequency (finest grating) that the child could resolve, which was recorded as the grating acuity score for that eye.

Children who could not resolve the coarsest standard acuity card grating (0.32 cycles/cm) were tested with the low vision card, which has 2.2-cm-wide black-and-white stripes filling 1 side of the card. The tester was permitted to display the low vision card at any distance, orientation, or location in the child’s visual field to determine whether the child had pattern vision in that eye.

Children were exempted from the visual acuity examination but not from data analysis if an ETROP Study–certified examiner and a parent agreed that both eyes had only light perception or worse vision and the child had bilateral retinal detachments, phthisis bulbii, or bilateral enucleations.

DATA ANALYSIS

Data were included only if treatment for any amblyopia (judged by the examining ophthalmologist) had been prescribed for at least 4 weeks before the acuity test and if refractive error (measured by cycloplegic retinoscopy) had been
measured and corrected within 3 months of the acuity test. Correction was required for myopia of at least 1.00 diopter (D), hyperopia of at least 4.00 D, or astigmatism of at least 1.50 D and for anisometropia of at least 1.50 D spherical equivalent or cylinder.

Grating acuity results were categorized as normal (≥13 cycles/degree), below normal (<13 cycles/degree and ≥6.4 cycles/degree), poor (measurable acuity <6.4 cycles/degree), or blind/low vision (only the ability to detect the 2.2-cm-wide stripes on the low-vision Teller acuity card at any distance and at any location in the visual field, light perception only, or no light perception). Visual acuities in the poor and blind/low vision categories were classified as unfavorable outcomes. CM indicates conventional management; ET, early treatment (treated at high-risk prethreshold).

Figure 2. Distribution of grating acuity outcomes for randomized eyes by treatment assignment. Normal indicates 13 or more cycles/degree; below normal, less than 13 to 6.4 or more cycles/degree; poor, measurable acuity of less than 6.4 cycles/degree; blind/low vision, ability to detect only the 2.2-cm-wide stripes on the low-vision Teller acuity card at any distance and at any location in the visual field, light perception only, or no light perception.

RESULTS

Of the 401 randomized infants, 370 survived until 6 years of age (Figure 1), and 329 (88.9%) had grating acuity assessed (n = 317) or were exempted from acuity assessment owing to bilateral blindness (n = 12). A total of 329 children were included in the data analysis. Of these, 260 children had symmetric (bilateral) disease, and 69 had asymmetric disease. Grating acuity data were incomplete for 8 children with symmetric disease and 4 children with asymmetric disease.

The proportion of randomized eyes with unfavorable grating acuity at 6 years of age is shown in Table 2. Overall, 18.1% of ET high-risk prethreshold eyes and 22.8% of CM eyes had unfavorable outcomes, a difference that did not reach statistical significance (P = .08). Within-subject comparisons in the children with bilateral disease showed that there were 30 children with favorable outcomes in their ET eyes and unfavorable outcomes in their CM eyes (discordant pairs), and 17 children with unfavorable outcomes in ET eyes and favorable outcomes in CM eyes. This difference approached but did not reach statistical significance (P = .06). Figure 2 provides the distribution of 6-year grating acuity outcomes by treatment assignment for randomized eyes.

We analyzed the grating acuity data using type 1 and type 2 categories, as proposed in the initial publication of ETROP Study results,1 and our results are shown in Table 3 for eyes that were high risk based on the RMRP2 algorithm.1 Type 1 high-risk prethreshold eyes receiving ET had a significantly lower rate of unfavorable outcomes (16.4%) than did type 1 eyes receiving CM (25.2%) (P = .004). In contrast, type 2 eyes that were high risk showed a higher, but not statistically different, percentage of unfavorable outcomes with ET (21.3%) than CM eyes (15.9%) (P = .29).

Results are shown for ET and CM type 1 (Figure 2A) and type 2 (Figure 2B) eyes. The data clearly indicate that there is a benefit of early treatment in type 1 eyes but not in type 2 eyes.
Table 4 presents the discordant pairs for grating acuity outcome at 6 years of age for subgroups of children with bilateral high-risk prethreshold ROP by International Classification of ROP category, RM-ROP2 risk, and types 1 and 2 disease. The greatest benefit of ET was seen in eyes with zone 1, stage 3, with or without plus disease. The benefit of ET was observed for all risk categories but was most pronounced in children with 30% to less than 45% risk for unfavorable outcome. This analysis also shows a significant benefit of ET for eyes with type 1 disease, but not for eyes with type 2 disease.

The results of grating acuity assessment of ET vs CM eyes with high-risk prethreshold ROP at 6 years of age in the ETROP Study are consistent with the results of ETDRS recognition acuity assessment at 6 years, indicating a clear benefit of ET in eyes with type 1 high-risk prethreshold ROP, but not in eyes with type 2 high-risk prethreshold ROP. In eyes with type 1 ROP, the rate of unfavorable grating acuity outcomes (ie, grating acuity <6.4 cycles/degree) was 16.4% in ET eyes compared with 25.2% in CM eyes ($P=0.004$). In contrast, the rate of unfavorable outcomes in eyes with type 2 high-risk prethreshold ROP was greater in ET compared with CM eyes (21.3% vs 15.9%).

The original design of the ETROP Study involved randomization of high-risk prethreshold eyes to ET or CM. The study showed a clear benefit for ET among high-risk prethreshold eyes. We also identified in 2003 that eyes could be segregated into 2 types according to the International Classification of ROP characteristics. Eyes with type 1 characteristics should receive ET and eyes with type 2 characteristics could be observed and treated if progression to type 1 occurred (Table 1). Most type 2 eyes have ROP that regresses and does not require treatment. The results for grating acuity at 6 years of age support these earlier recommendations. The results for grating acuity also are consistent with those reported for ETDRS acuity (optotype acuity) at 6 years of age. However, these grating acuity results differ from the grating acuity results at 9 months of age when a statistically significant difference was noted between ET and CM eyes. This is most likely due to dramatic visual development that occurs in the young child and the ability to detect more subtle differences at the older age.

The present report has strengths and limitations. The first strength is that grating acuity data could be obtained from nearly all study eyes. Only 10 of 298 ET eyes (3.4%)...
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and 10 of 291 CM eyes (3.4%) had no grating acuity score available. A second strength of the present study is the masking of the visual acuity testers to the treatment status and the current retinal status of each eye. A final strength is the high follow-up rate (342 patients [92.4%]), 6 years after their enrollment in the study, for the 370 surviving study participants. A disadvantage of assessment of grating acuity is that, in certain conditions that reduce optotype acuity (eg, amblyopia, age-related maculopathy, and retinal residua of ROP), grating acuity results may underestimate the loss in optotype acuity.

In conclusion, the grating acuity results at 6 years of age in children enrolled in the ETROP Study show an enduring benefit for early treatment for most eyes with ROP. However, this benefit exists only for eyes with type 1 disease. Looking at all eyes in the study, early treatment did not reach statistical significance when grating acuity was assessed but, when eyes were distinguished by type 1 or 2 characteristics, type 1 eyes showed a significant benefit for grating acuity outcome and type 2 eyes did not. This finding supports the ETDRS acuity outcome results, making careful observation and identification of the International Classification of ROP characteristics even more important as one contemplates whether laser ablation should be performed.


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