Original Article

JHSMR Journal of Health Science and Medical Research

Risk Factors for Poor Visual Outcome and Myopia in Retinopathy of Prematurity

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Received 16 December 2025 ● Revised 16 January 2026 ● Accepted 30 January 2026 ● Published online 23 September 2026

Abstract:

Objective: To identify risk factors for poor visual outcomes and myopia in stage 1–3 retinopathy of prematurity (ROP).

Material and Methods: Data from 116 patients with ROP (209 eyes) at a tertiary hospital between January 2011 and December 2020 were analyzed. Participants were categorized into three groups: observed, laser, and combined laser with intravitreal bevacizumab. Final visual acuity (VA) and refractive error changes with age and risk factors for poor visual outcomes and myopia were analyzed.

Results: The mean age at the last follow-up was 5.42±2.12 years. Median final refractive error (spherical equivalent) was 0.81 D (0.25, 1.38), 0.13 D (−2.0, 1.0), and −9.63 D (−13.25, −1.94), and median final logMAR VA was 0.18 (0, 1.3), 0.3 (0.1, 0.9), and 0.5 (0.18, 1.12), in the observed, laser, and combined groups, respectively. Individuals with severe ROP tended to develop high myopia at an early age. Multivariate analyses revealed treatment before postmenstrual age of 35 weeks, laser spots >600, and strabismus as risk factors for myopia <−3 D at age 3. The odds for myopia increased 2.37 times for every 100 laser spots. Risk factors for VA <20/40 were male sex, ROP requiring laser treatment, and strabismus.

Conclusion: Early ROP treatment, increased laser spots, and strabismus increase the risk of developing myopia and impaired VA at a young age.

Keywords: Bevacizumab, laser treatment, myopia, retinopathy of prematurity, strabismus, visual outcomes

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J Health Sci Med Res
doi: 10.31584/jhsmr.20261429
www.jhsmr.org

Introduction

Retinopathy of prematurity (ROP) is a complex disease for which positive outcomes depend on early diagnosis and intervention. The goal of ROP management is to promote normal ocular development and prevent visual impairment, as well as sequelae, such as myopia, strabismus, and amblyopia[1].

Current treatment guidelines for ROP, informed by the Early Treatment for Retinopathy of Prematurity (ETROP) study, have resulted in improved structural and visual outcomes[2]. However, conventional laser ablation is associated with peripheral visual field loss and often induces significant myopia. In contrast, intravitreal injections of anti-VEGF agents, such as bevacizumab, lead to rapid disease regression. Anti-VEGF therapy offers various advantages over laser therapy, including improved structural outcomes in zone I disease and a reduced risk of myopia[3-6]. Despite these benefits, challenges in primary anti-VEGF therapy remain, such as the need for retreatment and persistent peripheral avascular areas, which require prolonged follow-up time[1,7].

A combination of laser and intravitreal anti-VEGF therapy could represent an alternative approach, as it reduces the need for frequent follow-up visits. Therefore, the present study evaluated the long-term outcomes of ROP treatment and identified the risk factors for myopia and poor visual outcomes.

Material and Methods

The study protocol was approved by the Human Research Ethics Committee, Faculty of Medicine, Prince of Songkla University (REC 64-043-2-4). The need for informed consent was waived owing to the retrospective nature of the study. The medical records of infants diagnosed with ROP at our hospital from 1 January 2011 to 31 December 2020 were reviewed. All infants with stage 1-3 ROP and a follow-up period of 2 years or longer were included for analysis. The exclusion criteria were ROP stage 4 or 5, cataracts, and eyes undergoing retinal surgery. Figure 1 presents the study design.

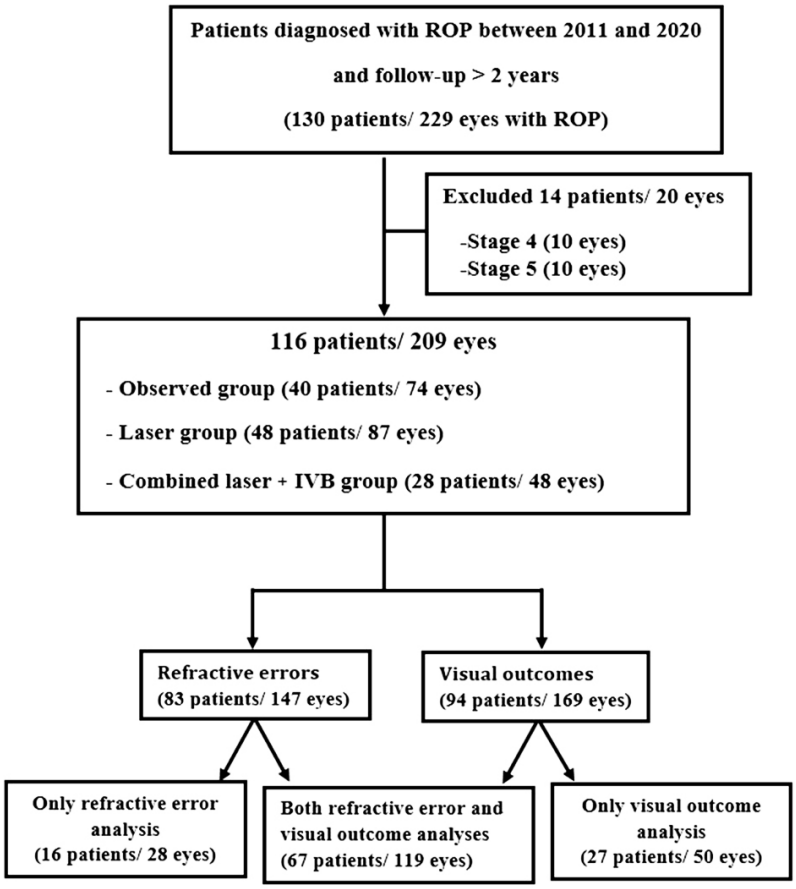
Participants were categorized into three groups according to the treatment modality: observed, laser, or combined. The treatment modality was selected by the attending ophthalmologists when ROP met the ETROP criteria. Infants with ROP who did not require treatment were included in the observed group. The age of treatment was determined based on the postmenstrual age (PMA) at the initial diagnosis of ROP for inborn infants or at the first presentation to our hospital for referred cases.

Laser therapy was performed with a large-spot, 810-nm diode laser (Iridex OcuLight SL; IRIDEX Co., Mountain View, CA, USA) ablating the avascular retina. In the combined group, infants underwent laser ablation with adjuvant intravitreal bevacizumab (IVB) at a dose of 0.625 mg (0.025 mL) during the same session.

After disease regression, visual acuity (VA), cycloplegic refraction, and orthoptic examinations were performed every 6 to 12 months. Refractive error data were recorded and converted into spherical equivalents (SE). Cycloplegic refractive errors at 3 years of age were analyzed to identify the risk factors for myopia (SE<-3.00 D). The degree of myopia was defined as follows: mild (SE -0.5 to -3 D), moderate (SE<-3 D to -5 D), and high myopia (SE<-5 D).

VA, corrected for refractive error, was measured and converted into the logarithm of the minimum angle of resolution (logMAR) for analysis. Preferential-looking tests were used in children who could not be assessed using an optotype chart. Only optotype VA was included in the analyses.

Statistical analyses were performed using STATA version 14 (StataCorp LP, College Station, TX, USA). For demographic and clinical data, p-value were calculated using Pearson's chi-squared test for categorical variables



ROP=retinopathy of prematurity

Figure 1 Study design

and one-way analysis of variance for continuous variables. Spherical equivalent refractive errors were compared using mixed-effects linear regression models, in which the patient and eye were considered random elements. p-values <0.05 were considered statistically significant for all comparisons. Definitive risk factors for visual outcomes and myopia were assessed using univariate and multivariate logistic regression with robust cluster to minimize the effect of inter-eye correlation within patients.

Results

A total of 116 infants were enrolled in the present study, and 209 eyes were included for analysis. Six eyes of three infants had different treatments in each eye and were excluded. The mean gestational age (GA) was 28.41±2.60 weeks, and the mean birth weight was 1132.67±375.25 g. The mean GA and birth weight were not significantly different in each group; however, the birth weight was smaller in the treatment group than in the other groups. The postnatal age at treatment was 2 weeks earlier in the combined group than in the other groups. Aggressive ROP (A-ROP) was observed in 6.7% (14/209) of eyes, all of which received combined treatment. The demographic characteristics of the groups are listed in Table 1.

Table 1 Demographic data of infants with retinopathy of prematurity

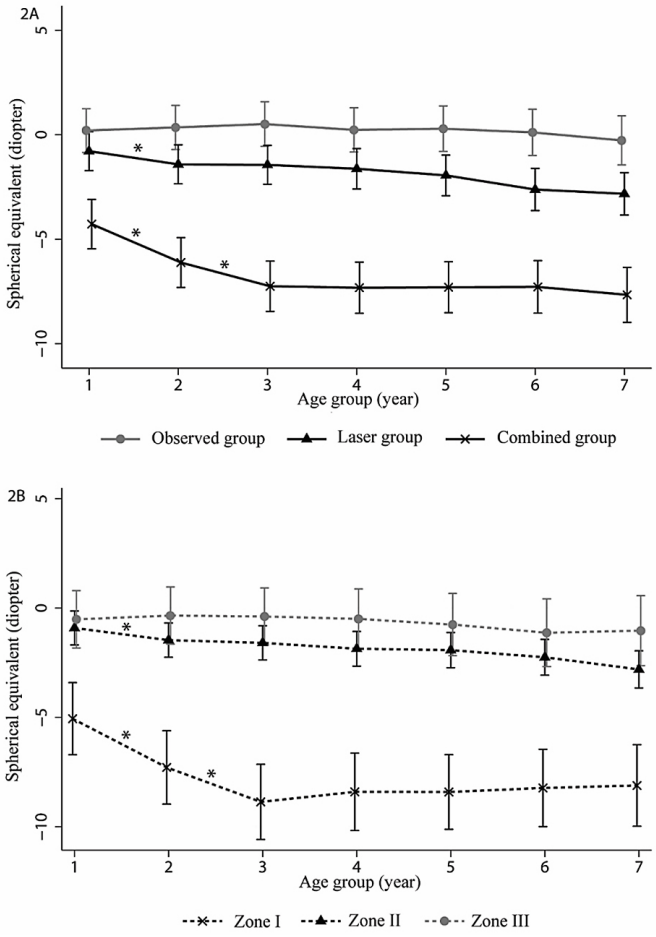
Demographic data	Overall	Treatment			
		Observed group n=40 pt/74 eyes (%)	Laser group n=48 pt/87 eyes (%)	Combined group n=28 pt/48 eyes (%)	p-value
Sex (pt)					
Male	63 (54.3)	26 (65.0)	20 (41.7)	17 (60.7)	0.067*
Female	53 (45.7)	14 (35.0)	28 (58.3)	11 (39.3)	
GA at birth (week)					
Mean±S.D.	28.41±2.60	28.80±2.76	28.04±2.10	28.46±3.11	0.395†
Median	28	29	28	29	0.392‡
(min, max)	(23, 36)	(23, 36)	(24, 33)	(23, 36)	
Birth weight (g)					
Mean±S.D.	1132.67±375.25	1237.50±455.65	1061.46±271.78	1105.00±3 80.97	0.081†
Median	1082.5	1135	1050	1000	0.283‡
(min, max)	(555, 2170)	(560, 2170)	(560, 1810)	(555, 1755)	
Birthplace (pt)					
Inborn	30 (25.9)	15 (37.5)	9 (18.8)	6 (21.4)	0.112*
Referral	86 (74.1)	25 (62.5)	39 (81.2)	22 (78.6)	
Age at last visit (years)					
Mean±S.D.	5.42±2.12	5.60±2.19	5.47 ± 2.13	5.07±2.02	0.583†
Median	5.08	4.95	5.60	4.99	0.644‡
(min, max)	(2.05, 10.33)	(2.10, 9.81)	(2.36, 10.33)	(2.05, 8.60)	
PMA at treatment (weeks)					
Mean±S.D.	37.14±3.44	37.85±3.75	37.23±3.60	35.96±2.28	0.080†
Median	37	37.5	38	36	0.071‡
(min, max)	(30, 49)	(32, 49)	(30, 45)	(32, 40)	
Age at treatment (months)					
Mean±S.D.	2.11±0.76	2.10±0.92[a]	2.34±0.61[a]	1.72±0.56[b]	0.002†
Median	2.03	1.85	2.47	1.67	0.001‡
(min, max)	(0.9, 5.4)	(0.9, 5.4)[a]	(1.03, 3.57)[b]	(1, 2.9)[a]	
Stage (eyes)					
Stage 2	8 (3.8)	8 (10.8)	0 (0)	0 (0)	0.001*
Stage 3	187 (89.5)	66 (89.2)	87 (100)	34 (70.8)	
A-ROP	14 (6.7)	0 (0)	0 (0)	14 (29.2)	
Zone (eyes)					
zone 1	23 (11.0)	0 (0)	0 (0)	23 (47.9)	<0.001*
zone 2	143 (68.4)	48 (64.9)	71 (81.6)	24 (50.0)	
zone 3	43 (20.6)	26 (35.1)	16 (18.4)	1 (2.1)	
Strabismus (pt)					
No	89 (76.7)	34 (85.0)	36 (75.0)	19 (67.9)	0.241*
Yes	27 (23.3)	6 (15.0)	12 (25.0)	9 (32.1)	
Strabismus (pt)					
Exotropia	18 (66.7)	3 (50.0)	10 (83.3)	18 (66.7)	0.253*
Esotropia	9 (33.3)	3 (50.0)	2 (16.7)	9 (33.3)	
Dragged disc/ macula (eyes)					
No	196 (93.8)	69 (93.2)	83 (95.4)	44 (91.7)	0.671*
Yes	13 (6.2)	5 (6.8)	4 (4.6)	4 (8.3)	

*=Pearson's chi-squared test, †=One-way ANOVA test, ‡=Kruskal–Wallis test
The a, b values in row not having a superscript in common differ significantly (p-value<0.05).
A-ROP=aggressive retinopathy of prematurity, GA=gestational age; IVB, intravitreous bevacizumab, PMA=postmenstrual age, pt=patient

In the laser group, most eyes had zone II ROP, with 88.5% (77 eyes) exhibiting the plus sign. In the combined group, approximately one-third of eyes had A-ROP, whereas almost half had zone I ROP. The total number of laser spots in the combined group was nearly double that of the laser group. All eyes in the combined group had a single dose of IVB, and 42 eyes had IVB injection and laser treatment in the same setting. Six eyes received IVB as primary treatment owing to unstable conditions, undilated pupils, and poor visibility, followed by laser ablation within one month.

Refractive outcomes

The mean age at the last follow-up was 5.42±2.12 years, and the median number of refraction visits was 5. The observed group had mild refractive error through preschool age, compared to a slow progression of myopia in the laser group. The combined group exhibited initial high myopia with rapid progression during the first 3 years of age, followed by stabilization (Figure 2A). The mean myopic changes in the combined group were −1.84 D and −1.14 D in the second and third years of age (Supplementary Table 1). By age 3, the prevalence of high myopia in all



*=Statistically significant differences from baseline

Figure 2 Changes in refractive error with age by treatment modality (A) and zone of retinopathy of prematurity (B) using a mixed-effect linear regression model

children with regressed ROP was 24% (35/147 eyes), with 72% (23/32) and 16% (11/69) in the combined and laser groups, respectively. At the final measurement, the median SE was 0.81 D (0.25, 1.38), 0.13 D (−2.0, 1.0), and −9.63 D (−13.25, −1.94) in the observed, laser, and combined groups, respectively (p−value<0.001). Regarding the ROP zone, the median SE were −10.88 D (−14.38, −5.5), 0.25 D (−3.50, 1.13), and 0.63 D (0, 1.13) in zones I, II, and III, respectively (p−value<0.05, Figure 2B).

Available refraction data at age 3 years from 83 participants (147 eyes) were analyzed to identify risk factors for myopia (SE<−3.00 D, Table 2). Univariate analyses identified treatment before PMA of 35 weeks, treatment before 2 months of age, treatment group, zones I and II, plus sign, total number of laser spots greater than 600, and the presence of strabismus as risk factors associated with myopia. However, in the multivariate analyses, treatment before PMA of 35 weeks, a total number of laser spots greater than 600, and the presence of strabismus were retained as significant risk factors for myopia. Notably, the odds of myopia increased by 2.37 times for every 100 laser spots.

Visual outcomes

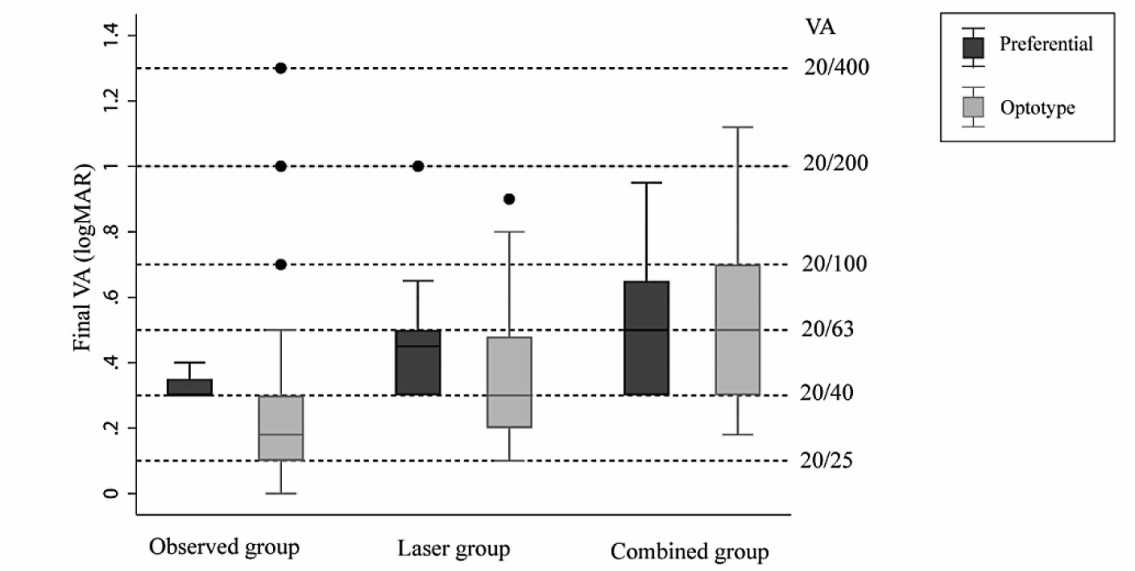
At the final visit, the median VA (optotype) in the observed, laser, and combined groups was logMAR 0.18 (0, 1.3) (20/30), 0.3 (0.1, 1) (20/40), and 0.5 (0.18, 1.12) (20/63), respectively (p−value<0.001, Figure 3).

VA data from 169 eyes of 94 participants were analyzed to identify predictive factors for poor visual

Table 2 Robust logistic regression analysis for predicting factors associated with myopia <−3 D at 3 years of age

Demographic data	Univariate		Multivariate	
	cOR (95% CI)	p−value	aOR (95% CI)	p−value
Sex				
Female	1		1	
Male	1.38 (0.53, 3.61)	0.511	3.35 (0.94, 11.91)	0.062
PMA at treatment				
>35 weeks	1		1	
≤35 weeks	3.24 (1.15, 9.17)	0.027	4.88 (1.01, 23.76)	0.049
Age at treatment				
>2 months	1		1	
≤2 months	2.35 (1.01, 5.13)	0.041	0.78 (0.20, 3.05)	0.719
Treatment modality				
Laser	1		1	
Combined	9.94 (2.94, 33.62)	<0.001	2.26 (0.52, 9.85)	0.277
Observed	0.07 (0.01, 0.59)	0.014	0.34 (0.06, 1.90)	0.219
Zone				
zone 3	1		1	
zone 2	12.97 (1.67, 99.22)	0.014	3.29 (0.37, 29.29)	0.286
Number of laser spots				
≤600	1		1	
>600	9.73 (3.13, 30.28)	<0.001	9.96 (1.81, 54.71)	0.008
Number of laser spots (per 100 spots)	1.98 (1.38, 2.84)	<0.001	2.37 (1.19, 4.73)	0.014
Strabismus				
No	1		1	
Yes	2.53 (0.94, 6.84)	0.066	7.11 (1.90, 26.60)	0.004

A−ROP=aggressive retinopathy of prematurity, aOR=adjusted odds ratio, cOR=crude odds ratio, CI=confidence interval, PMA=postmenstrual age



VA=visual acuity

Figure 2 Boxplot for visual acuity of children with retinopathy of prematurity at the final visit

outcomes (VA <20/40, Table 3). Univariate analyses revealed laser and combined treatment group, zone 1, A-ROP, plus sign, total number of laser spots greater than 600, and strabismus as risk factors associated with VA <20/40. In the multivariate analyses, male sex, laser treatment group, and strabismus were identified as statistically significant risk factors. However, there was no significant difference in risk of poor visual outcome between eyes that underwent the combined treatment and laser group (aOR= 0.66, p-value=0.49).

Sequelae

Strabismus was identified in 23% (27/116) of children with ROP, with 25% (12/48) and 32% (9/28) in the laser and combined groups, respectively. Exodeviation was more prevalent than esodeviation in the treatment group. Dragged discs were noted in 4-8% of eyes with ROP, and no significant difference was found between the observed group and the treatment groups (Table 1).

Discussion

In the present study, laser ablation was the primary treatment for ROP and was combined with bevacizumab in severe diseases, including zone I and A-ROP. Myopia development was related to the early age of treatment and the number of laser spots, with these treatments affecting the final VA. The prevalence of high myopia (<-5 D) at 3 years of age was 26.6% (34/147 eyes) in the treatment group, with 16% of eyes in the laser group and 72% of eyes in the combined group. In comparison, in a previous study analyzing zone 1 ROP treated with laser at 4 years of age, the prevalence of high myopia was 47.6%[8].

The refractive changes in the combined group exhibited high myopia and a rapid myopic shift in the early years of life, in contrast to a lower degree of myopia and slower progression until 7 years of age in the laser group. This myopic progression in the combined group is similar to that observed in children with severe ROP treated with laser only, without IVB use, in previous reports[4,8-11]. This

Table 3 Robust logistic regression analysis for predicting factors associated with poor visual outcome VA (<20/40)

Demographic data	Univariate		Multivariate	
	cOR (95% CI)	p-value	aOR (95% CI)	p-value
Sex				
Female	1		1	
Male	1.53 (0.68, 3.45)	0.309	2.77 (1.07, 7.17)	0.036
PMA at treatment				
>35 weeks	1		1	
≤35 weeks	1.73 (0.72, 4.17)	0.219	1.94 (0.59, 6.34)	0.276
Treatment modality				
Laser	1		1	
Combined	2.88 (1.05, 7.75)	0.031	0.66 (0.21, 2.14)	0.491
Observed	0.19 (0.06, 0.59)	0.004	0.20 (0.03, 0.91)	0.037
Zone				
zone 3	1		1	
zone 2	1.52 (0.54, 4.33)	0.429	1.17 (0.29, 4.76)	0.830
zone 1	16.25 (1.44, 183.97)	0.024	6.83 (0.44, 106.98)	0.171
Stage				
Stage 2	1		1	
Stage 3	1.44 (0.15, 13.90)	0.752	3.90 (0.47, 32.04)	0.206
A-ROP				
Yes	1		1	
No	0.05 (0.01, 0.43)	0.006	0.14 (0.004, 3.97)	0.247
Number of laser spots				
≤ 600	1		1	
>600	2.49 (1.08, 6.33)	0.046	2.06 (0.61, 6.30)	0.258
Number of laser spots (per 100 spots)	1.20 (1.05, 1.36)	0.006	1.09 (0.92, 1.29)	0.334
Strabismus				
No	1		1	
Yes	5.55 (2.23, 13.81)	<0.001	6.92 (2.38, 19.66)	<0.001

A-ROP=aggressive retinopathy of prematurity, aOR=adjusted odds ratio, cOR=crude odds ratio, CI=confidence interval, VA=visual acuity, PMA=postmenstrual age

result suggests that IVB did not affect myopic development in severe ROP. We observed no significant differences in the GA or birth weight among infants in the treatment groups. However, the combined group was treated 2 weeks earlier than the laser group and received twice as many laser spots. This difference could be attributed to the large area of the avascular retina at the time of treatment in the combined group. Children with anterior zone II ROP were more likely to undergo laser treatment only and had fewer laser spots than the combined group. However, zone II ROP classification was not detailed in the present study.

Consistent with several previous studies[4,12-16], numerous laser spots, greater than 600, significantly increased the risk of myopia in the present study. In addition, our results indicated that myopia was significantly associated with the timing of laser treatment before 35 weeks, suggesting that myopia correlated with the treatment of the immature retina. Contrary to another cohort study, delaying laser treatment after IVB reduces the number of laser spots, and myopic progression persists[4].

Regarding visual outcomes, VA in the observed, laser, and combined groups was 0.18 (0,1.3), 0.3 (0.1, 0.9), and 0.5 (0.18, 1.12), respectively. Children with ROP who did not receive treatment had significantly better VA than those who received treatment. However, VA did not significantly differ between the laser and combined groups.

A previous study in children with ROP and extremely low birth weight revealed that patients with zone I ROP exhibit more impaired VA than others, with a significant correlation between best corrected VA and myopic status[10]. Similarly, in the present study, children with zone I ROP undergoing combined treatment also exhibited worse VA and more myopia than those in the other groups. However, we did not evaluate the relationship between VA and refractive error.

In the present study, the risk factors for VA <20/40 in the multivariate analysis include male sex, laser treatment, and the presence of strabismus. This result was consistent with previous studies demonstrating that impaired vision is associated with treatment-requiring ROP[17]. Another study indicated that VA and foveal morphology are affected by laser treatment and early GA[18]. The small number of dragged discs was reported in both treated and untreated ROP in this study; visual impairment could partly be attributed to foveal maldevelopment. Although the combined group was treated earlier and had a larger area of laser ablation compared to the laser group, the visual outcome did not differ significantly. Other longitudinal studies have demonstrated that children with ROP had delayed development of VA and improved with age regardless of the treatment modality[4,11].

In the present study, the prevalence of strabismus among children with ROP was 23%, predominantly exotropia (67%). Strabismus was significantly associated with impaired vision and myopia. In contrast to previous studies demonstrating higher rates of strabismus (34–42%) with a predominance of esotropia[17,19,20], treatment-required ROP had a strong impact on strabismus in our study. However, greater GA at birth or later postnatal age at treatment reduced the risk[20]. These findings may be confounded by other factors that increase the risk of strabismus, such as prematurity, amblyopia, anisometropia, macula dragging, and neurodevelopmental status.

This retrospective study has some limitations. First, the treatment selection led to bias towards the laser or combined treatment in severe disease. The total number of laser spots may vary considerably due to spot size, density, and missing spots when performing laser indirect ophthalmoscopy, particularly with a hazy fundus view or in severe cases. VA and refraction were measured at different time points. Additionally, the difference in anisometropia and astigmatism between groups was not assessed and could have contributed to visual outcomes. Finally, this study did not include infants with anti-VEGF monotherapy; therefore, the effect of anti-VEGF agents on myopia and visual outcomes could not be evaluated. Thus, further studies should focus on the timing of laser treatment and whether delaying laser treatment after anti-VEGF injection could improve refractive outcomes.

In conclusion, the present study demonstrated that laser treatment for ROP significantly affected visual outcomes. Myopic progression was associated with the timing of treatment and the extent of laser application. Strabismus was a predictive factor related to myopia and impaired VA. Our findings highlight that children with severe ROP should be closely monitored for early detection of refractive error and strabismus.

Acknowledgement

We want to thank all individuals who assisted in data collection and statistical analysis, Dr. Alan Geater, Epidemiology Unit, Faculty of Medicine, Prince of Songkla University, Ms. Sujinda Damthong, and Ms. Nunnapat Prupeachkae.

Funding sources

This study did not receive any funding.

Conflict of interest

The authors have no conflicts of interest to declare.

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