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Comparison of Success Rates Between Laser Photocoagulation and Intravitreal Anti-Vascular Endothelial Growth Factor Injection for the Treatment of Retinopathy of Prematurity in a Tertiary Referral Center: An 11-Year Survey

Osman Ahmet Polat,[1] Hidayet Sener,[1] Cagatay Karaca,[1] Fatih Horozoglu,[1] Muhammed Enes Gurbuz,[1] Cem Evereklioglu[1]

[1]Department of Ophthalmology, Erciyes University Faculty of Medicine, Kayseri, Türkiye

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Address for correspondence:
Osman Ahmet Polat.
Department of Ophthalmology, Erciyes University Faculty of Medicine, Kayseri, Türkiye
Phone: +90 555 722 67 55
E-mail: osmanahmet@gmail.com

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ABSTRACT

Objective: To compare the success and reactivation rates between laser photocoagulation and intravitreal anti-VEGF injection for the treatment of retinopathy of prematurity (ROP).

Materials and Methods: A total of 434 patients with ROP were included in the study, with 299 treated with laser photocoagulation (group 1) and 135 treated with intravitreal anti-VEGF injection (group 2). Outcome measures included birth weight, gestational age, disease stage, presence of plus disease, type of first intervention, time of postpartum ROP onset, date and time of recurrence after the first intervention, type of second intervention following recurrence, and sex.

Results: Laser photocoagulation (LP) was performed in 299 premature patients, and intravitreal anti-VEGF injection was the first intervention in 135 patients. The overall reactivation rate for ROP after treatment was 6.5% (n=28). The reactivation rates for group 1 and group 2 were 3.7% (n=11) and 12.6% (n=17), respectively, with the difference being significant ($p<0.001$). Over the past 11 years, there has been a shift from laser treatment to anti-VEGF therapy, with anti-VEGF therapy linked to a 3.77-fold higher risk of reactivation. Low birth weight, low gestational age, and aggressive posterior ROP were identified as factors contributing to an elevated risk of reactivation. The median time to reactivation was similar for both group 1 and group 2 patients ($p>0.05$).

Conclusion: Both laser application and anti-VEGF injection were effective for the treatment of ROP. However, initial LP has a lower reactivation rate.

Keywords: Anti-vascular endothelial growth factor, laser, reactivation, retinopathy of prematurity, success rate.

INTRODUCTION

Retinopathy of prematurity (ROP) is a disease characterized by the abnormal proliferation of retinal vasculature in premature infants, which can lead to blindness. The global prevalence

of blindness attributable to ROP is 1 in 50,000 cases.[1] Birth weight (BW) and gestational age (GA) have consistently been shown to be the primary risk factors for ROP. Advances in neonatal care, ROP screening programs, and treatments have reduced ROP-related blindness by 3% to 11% of childhood blindness.[2]

In premature infants, normal vascular development is disrupted by preterm birth. Vascular endothelial growth factor (VEGF) and hypoxia-inducible factor-1-alpha (HIF-1α) are released from avascular retinal tissue, inducing neovascularization. This neovascularization can progressively lead to tractional retinal detachment over time.[3-5] Treatment decisions for ROP are based on disease stage, retinal zone, and the presence of plus disease. Current treatment options include laser photocoagulation (LP) and intravitreal anti-VEGF injections.[2,6] LP therapy reduces VEGF secretion by ablating the avascular retina, while anti-VEGF agents block VEGF.[7]

This study aimed to compare the success rates between LP and anti-VEGF injections for the treatment of premature infants with ROP in a tertiary care center over the past 11 years and to evaluate the impact of multiple risk factors on these outcomes.

MATERIALS AND METHODS

Medical records of patients who underwent LP (group 1) or anti-VEGF injections (group 2) for the treatment of retinopathy of prematurity (ROP) were retrospectively reviewed in this cohort study at the Medical and Surgical Retina Service of Erciyes University Medical Faculty between 2011 and 2021. All procedures performed on human subjects complied with the Helsinki Declaration of 1964. The study was approved by the Erciyes University Clinical Research Ethics Committee (Approval Number: 2023/117, Date: 08.02.2023).

The International Classification of ROP, second edition (ICROP2), was used to define the disease stage of ROP.[8] In Turkey, all infants with a GA below 34 weeks or BW ≤1700 grams should be screened for ROP according to the criteria established by the Turkish Society of Neonatology and the Turkish Society of Ophthalmology.[9] Criteria for discontinuation of ROP follow-up included complete retinal vascularization up to the ora serrata and peripheral zone III vascularization in the absence of previous zone I or II ROP. Treatment requiring reactivation was defined as the development of new stage 3 disease (extraretinal neovascularization) at a new or previous ridge, or new plus disease with marked vascular dilatation and tortuosity after initial post-treatment remission. The first regression was accepted as the regression of plus disease and extraretinal neovascularization. Additional treatments within 2 weeks after the first laser treatment for skip areas were not classified as reactivation. Initial treatments were performed bilaterally, and reactivation in either eye was accepted as a reactivation criterion. The success of the study was defined as complete retinal vascularization with an attached retina.

KEY MESSAGES

- Both laser therapy and anti-VEGF therapy were effective as first-line treatments and rescue treatments after reactivation for ROP.
- The overall reactivation rate after treatment was 6.5%. Anti-VEGF therapy was associated with a 3.77-fold increased risk of reactivation.
- Low birth weight, low gestational age, and APROP were associated with a higher risk of reactivation. The median time to reactivation was similar in both the laser and anti-VEGF groups.

The treatment decision was made according to the Early Treatment for Retinopathy of Prematurity (ETROP) recommendations.[10] After diagnosis, therapeutic intervention was initiated within 24 hours for aggressive posterior ROP (APROP) and within 48 hours for other treatment-requiring stages of ROP. All LP procedures were performed under general anesthesia.

The protocol for group 1 eyes receiving LP was as follows: before laser ablation, pupils were dilated with 0.5% cyclopentolate and 2.5% phenylephrine eye drops. Ablation was performed with an 810 nm diode laser attached to an indirect ophthalmoscope (Iridex Corporation, Germany) using a 28 D lens. The entire avascular retina was treated with adjacent laser burns. The laser power was adjusted to produce slightly whitish laser burns while avoiding overly white-hot burns. Topical dexamethasone drops were prescribed postoperatively.

The anti-VEGF injection protocol for group 2 eyes was as follows: After applying 10% povidone-iodine (PI) to the skin, 5% PI was applied to the ocular surface and conjunctival sac, which was allowed to settle for 3 minutes. An intravitreal injection was then administered using a 30-G needle inserted perpendicularly to the eye, 1 mm posterior to the limbus. The administered dose of the anti-VEGF agent was 0.625 mg/0.025 mL for bevacizumab and 0.25 mg/0.025 mL for ranibizumab (Lucentis, Novartis Pharma GmbH, Nuremberg, Germany). All intravitreal injections were performed under an operating microscope, and moxifloxacin eye drops were prescribed for ten days postoperatively.

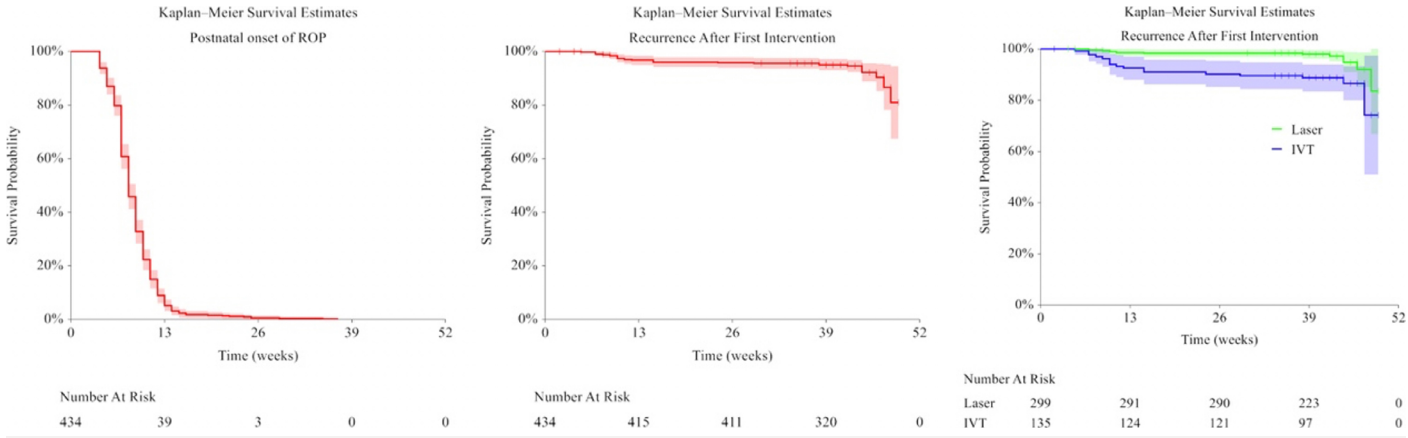

Figure 1. Kaplan-Meier estimates for the onset of ROP and reactivation of ROP after the first intervention.

Statistical Analysis

The outcome measures for both groups included BW, GA, disease stage, presence of plus disease, type of first intervention, time of postpartum ROP onset, date and time of recurrence after the first intervention, type of second intervention following recurrence, and gender. Statistical analysis was performed using SPSS version 22 (IBM, Chicago, USA). The Kolmogorov-Smirnov normality test was applied to the dataset. Pearson's chi-square and Fisher's exact tests were used for nominal and ordinal data. The Kaplan-Meier method was employed to estimate the median time to onset of primary ROP and reactivated ROP. The log-rank test was used to compare the median difference in reactivation time after the first intervention between LP and anti-VEGF injection. Univariate and multivariate logistic regression analyses were performed to evaluate the relationship between GA, BW, and the occurrence of recurrence. Data are presented as mean ± standard deviation or median (25–75% interquartile range).

RESULTS

A total of 434 infants (247 boys, 187 girls) treated for retinopathy of prematurity (ROP) were included in the study. The median BW was 1050 grams (range: 875–1350) and the median GA was 28 weeks (range: 26–30). Sixteen patients had stage 2+ plus disease (3.7%), 312 (71.9%) had stage 3+ plus disease (36.9%), and 106 APROP disease (24.4%).

The median time to ROP onset was the 8th week (95% CI: 7.6–8.3) after birth (Fig. 1). LP was performed in 299 patients, and anti-VEGF treatment was administered as the first intervention in 135 patients. The overall reactivation rate for ROP after treatment occurred in 28 (6.5%) patients (Fig. 1). However, when the reactivation rates were compared between the two groups, eyes treated with LP had a lower estimated reactivation rate (3.7%, n=11) compared to eyes treated with anti-VEGF (12.6%, n=17), and the difference was significant (p<0.001) (odds ratio: 0.265, 95% CI: 0.121–0.543) (Fig. 1). The median reactivation time after the first procedure was 9 weeks (95% CI: 7.7–10.2), with no significant difference (p=0.170) between LP [8th week (95% CI: 4.7–11.2)] and anti-VEGF injection [10th week (95% CI: 8.4–11.5)] regarding the median reactivation time after the first procedure in patients with reactivated ROP.

Table 1. *Post-hoc* comparison of reactivation rate by stage

Comparison	p	Bonferroni adjusted p-value
Stage 2+ plus disease - Stage 3+ plus disease	<0.001	0.467
Stage 2+ plus disease - APROP		0.074
Stage 3+ plus disease - APROP		<0.001

APROP: Aggressive posterior retinopathy of prematurity.

Reactivation was observed in 13 of 119 (10.9%) bevacizumab-treated infants and 4 (25%) of 16 ranibizumab-treated infants (p=0.111). There was no significant difference in the risk of reactivation between bevacizumab and ranibizumab (odds ratio: 0.368, 95% CI: 0.103–1.134, p=0.245). The median time to reactivation after bevacizumab and ranibizumab was the 10th week (95% CI: 8.8–11.1) and 8th week (95% CI: 6.0–9.9), respectively (p=0.315).

When reactivation rates were evaluated according to the stages of ROP, there was no reactivation in stage 2+ plus disease, 3.2% (10/312) in stage 3+ plus disease, and 17.0% (18/106) in APROP (p<0.001). The post hoc comparison of reactivation rates by stage is shown in Table 1. There was no difference between LP and anti-VEGF therapy when evaluating the risk of ROP reactivation for the first intervention by stage

Table 2. Reactivation rates by ROP stage and initial intervention

ROP stage	Stage 2+ plus disease		Stage 3+ plus disease		APROP		All stages	
Intervention	Laser	Anti-VEGF	Laser	Anti-VEGF	Laser	Anti-VEGF	Laser	Anti-VEGF
Reactivated disease	–	–	6 (2.3%)	4 (7.0%)	5 (16.0%)	13 (17.0%)	11 (3.7%)	17 (12.6%)
No reactivation	13	3	249 (97.7%)	53 (93.0%)	26 (84.0%)	62 (83.0%)	288 (96.3%)	118 (87.4%)
p value*	–		0.07		0.881		<0.001	

*: Chi-square test for treatment selection. APROP: Aggressive posterior retinopathy of prematurity; VEGF: Vascular endothelial growth factor.

(Table 2). Reactivation rates by ROP stage and intervention type are shown in Figure 2 and Table 2.

LP as a second intervention was performed in 10 of 17 patients who reactivated after anti-VEGF injection; re-injection as a second intervention was performed in the remaining 7 patients. In 11 reactivated ROP patients treated with LP as the first intervention, 7 received anti-VEGF injection as a second intervention, and 4 received LP. None of the patients treated for reactivation had a second reactivation during follow-up.

BW was categorized into two groups (≤1000 g vs >1000 g). In univariate logistic regression, BW ≤1000 g was associated with higher odds of ROP reactivation (odds ratio [OR] 5.23, 95% confidence interval [CI] 1.93–14.18; p<0.001). Each additional week of GA was associated with lower odds of reactivation (OR 0.77, 95% CI 0.64–0.94; p<0.001). In the multivariable logistic regression model including both BW and GA, BW ≤1000 g remained associated with higher odds of reactivation (OR 4.21, 95% CI 1.19–14.90; p=0.026), whereas GA was not significantly associated with reactivation (OR 1.07, 95% CI 0.83–1.37; p=0.605).

The change in the initial treatment approach by year is shown in Figure 3a, and the reactivation rates by year are shown in Figure 3b. Over the years, the rate of LP has decreased, and anti-VEGF therapy appears to have become the predominant treatment.

Two patients treated with LP underwent surgery due to progression to stage 4 disease. One patient treated with anti-VEGF injection developed pre-macular fibrosis and underwent vitreoretinal surgery for an epiretinal membrane. These patients were referred from other clinics due to late-stage 3+ plus disease or APROP. They were considered as progression cases and were not included in the reactivation analysis of the 434 patients. One patient experienced anterior segment ischemia, and one patient had a corneal burn after LP.

As this was a retrospective comparative cohort study, no sample size calculation was performed before the study. A post hoc power analysis was performed using the observed reactivation rates (LP: 11/299 [3.7%] vs anti-VEGF: 17/135 [12.6%]) with a two-sided α=0.05 for the between-group comparison of proportions. Using Cohen's h effect size (0.34) and the effective sample size (93.0), the achieved power was 90.6%.

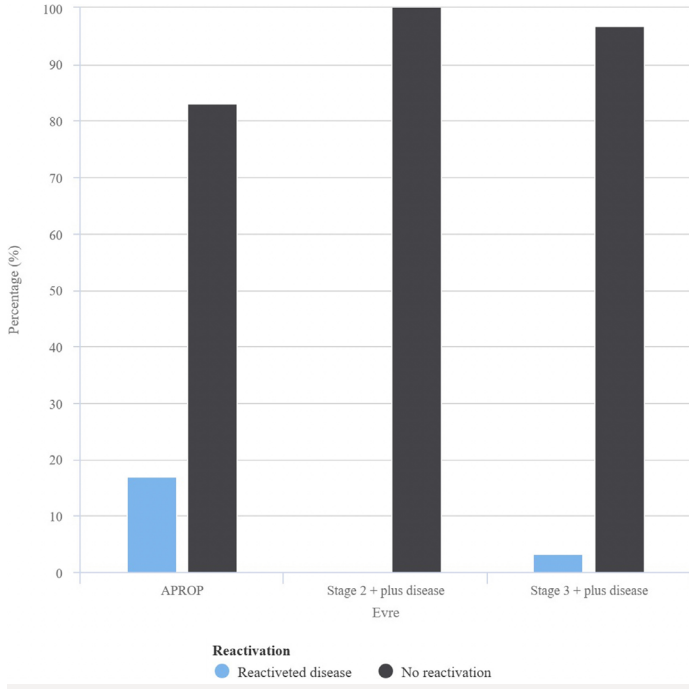

Figure 2. Reactivation rates by stage of ROP.

DISCUSSION

Both LP and anti-VEGF injections are commonly used for the treatment of retinopathy of prematurity (ROP).[6,11,12] The reactivation rate of LP treatment applied for stage 3+ disease in the BEAT-ROP trial was 26%,[4] and there was a 17.4% reactivation rate following LP treatment for APROP disease.[13] The rate of adverse outcomes for patients with type 1 ROP treated with LP in the ETROP study was reported as 9.1%.[14] The reactivation rate observed with bevacizumab treatment in the BEAT-ROP study was 6%, and LP was associated with a 5.88-fold higher risk of reactivation.[4] Although the RAINBOW study showed that the reactivation rate with ranibizumab therapy was lower than with LP therapy in stage 3+ disease, the risk of

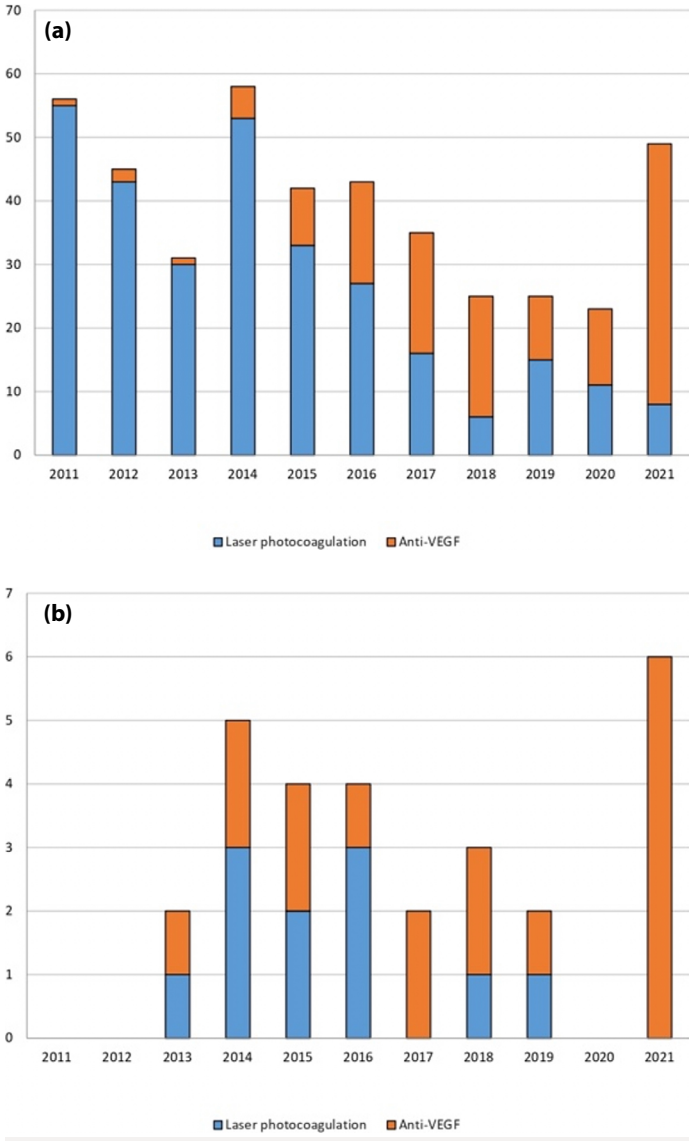

Figure 3. (a) Rates of laser photocoagulation therapy and anti-VEGF therapy by year. **(b)** Reactivation rates by year.

reactivation was statistically similar.[15] In this study, the overall reactivation rate for ROP after treatment was 6.5% (n=28).

A recent network meta-analysis compared the reactivation rates of bevacizumab, ranibizumab, aflibercept, and LP therapy and found that LP therapy was superior to ranibizumab treatment in zone I and II ROP. Bevacizumab therapy was associated with less reactivation than LP therapy in zone I ROP.[6] Fewer ocular side effects have been reported with anti-VEGF therapy in zone I disease compared to LP.[16,17] In our study, LP was associated with a lower estimated risk of reactivation compared to anti-VEGF therapy (Table 2). The relatively lower reactivation rate with LP therapy may be due to more proactive treatment decisions by ROP specialists. Other possible reasons may include differences between pediatric units in various medical centers.[18] A network meta-analysis found no statistical differences between the ranking probabilities of three anti-VEGF agents.[6] Bevacizumab remains the most commonly used agent for off-label treatment, while ranibizumab is an FDA-approved agent based on the RAINBOW trial.[15] However, there is still no consensus in the literature regarding which anti-VEGF agent should be used. Additionally, the appropriate dose of anti-VEGF for ROP treatment remains a topic of debate.

The median reactivation time after initial treatment was the 8th week for LP therapy and the 10th week for anti-VEGF treatment (8th week for ranibizumab, 10th week for bevacizumab) in this study. In the BEAT-ROP trial, the median reactivation time was 6.4–6.8 weeks for LP therapy and 14.4–19.2 weeks for bevacizumab therapy.[4] In the RAINBOW trial, the median reactivation time was the 8th week for ranibizumab therapy.[15] Another report showed an earlier reactivation time for ranibizumab compared to bevacizumab.[19] In the network meta-analysis, the median reactivation time was longer for bevacizumab therapy than for ranibizumab therapy.[6] The main advantage of anti-VEGF therapies over LP therapy is the rapid clearance of VEGF from the vitreous and the quick regression of the disease.[20] Additionally, bevacizumab is cleared from the vitreous later than ranibizumab.[21-24] LP therapy destroys the VEGF-producing avascular retina but does not have an immediate effect on secreted VEGF.[25] Because VEGF may not be completely blocked with LP therapy compared to anti-VEGF therapy, the reactivation threshold may have been reached earlier. Although not statistically significant, it can be predicted that the median reactivation time would be shorter for LP therapy, followed by ranibizumab and bevacizumab, respectively.

In a retrospective analysis of 436 premature infants in the intensive care unit, risk factors for ROP were evaluated using multivariate regression, and it was reported that the most effective variable was GA, followed by BW.[26] In a study evaluating risk factors for progression to stages 4 and 5 in ROP patients who received LP treatment, sepsis, oxygen therapy, and a history of mechanical ventilation were found to be effective factors.[27] Our analysis further showed that BW and GA may also be effective in predicting reactivation of ROP.

In our center, there was a trend toward anti-VEGF treatment over LP over the last 11 years. This finding is similar to a previously published study that described treatment trends from 2001 to 2017 in Germany.[28] Over the years, anti-VEGF injections have gained increasing acceptance in the treatment of ROP. The advantages of anti-VEGF therapy over LP therapy

include a lower requirement for technical expertise, a reduced risk of myopia progression, the potential for continued retinal vascularization, and possibly improved peripheral vision.[29,30] Additionally, during the COVID-19 pandemic, anti-VEGF injections allowed for a shorter procedure time, reducing the risk to operating room staff. An asymptomatic COVID-19-positive patient requiring treatment for ROP could be rapidly treated with anti-VEGF under topical anesthesia in our study in 2020. In our series, anti-VEGF was the most preferred treatment in 2021. However, reactivation after anti-VEGF remains an important issue, and even when reactivation occurs after anti-VEGF treatment, it usually happens in a new peripheral ridge, which allows for less retinal ablation if LP therapy is chosen as an additional treatment.

When comparing reactivation rates between stages, a significantly higher reactivation rate was observed in APROP compared to stage 3 disease (Table 1). Stage 2 disease with plus is generally a posterior disease, which may explain why the activation rate was not significantly different compared to APROP. The increased reactivation rate in APROP may be attributed to the highly posterior localization of the disease in zone I and posterior zone II. APROP patients had a larger extent of avascular retinal area, which may contribute to a higher degree of VEGF upregulation after anti-VEGF therapy. Even after LP therapy, a longer duration may be required for VEGF to be cleared. This could explain the higher reactivation rate after treatment of APROP disease. However, the choice of treatment for each stage did not affect the reactivation rate. Indeed, there was no difference in reactivation rates between LP and anti-VEGF treatment for APROP (Table 2). APROP is a very active posterior disease with no significant ridge in a zone, so the zone of the disease may be more important than the stage of the ridge.

The primary limitation of this study was its retrospective design. However, the strength of this study lies in its large sample size and single-center setting, with consistent follow-up and treatment protocols.

CONCLUSION

This study demonstrated that both LP and anti-VEGF therapy were effective options for the treatment of retinopathy of prematurity (ROP). They also served effectively as rescue treatments in reactivated patients. The overall reactivation rate following treatment was observed to be 6.5%. The reactivation rate was 3.7% in the LP group and 12.7% in the anti-VEGF group. Anti-VEGF therapy was linked to a 3.77-fold higher risk of reactivation. Low BW, low GA, and APROP were found to be factors associated with a higher risk of reactivation. The median time to reactivation was similar in the LP and anti-VEGF groups. However, further research with longer follow-up is needed, as late reactivation can occur with anti-VEGF therapy.

Ethics Committee Approval: Ethics committee approval was obtained from Erciyes University Clinical Research Ethics Committee (Approval Number: 2023/117, Date: 08.02.2023).

Informed Consent: Written informed consent was obtained from the parents.

Conflict of Interest: The authors have no conflicts of interest to declare.

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