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Longitudinal observation of ocular biometric parameters after intravitreal ranibizumab injection for retinopathy of prematurity

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早产儿视网膜病变玻璃体腔注射雷珠单抗后眼部生物测量参数的纵向观察

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摘要

目的:评估早产儿视网膜病变(ROP)患儿接受玻璃体腔注射雷珠单抗(IVR)治疗后,在出生后第1 a内眼部生物测量参数的纵向变化。

方法:对诊断为1型ROP的早产儿进行了一项为期1 a的纵向观察性对比研究。治疗组患儿接受雷珠单抗注射治疗,对照组不进行任何干预。所有患儿分别在矫正胎龄(GA)0(即孕周40 wk)、3、6和12 mo时接受A超生物测量检查,测量前房深度(ACD)、晶状体厚度(LT)、玻璃体腔深度(VCD)和眼轴长度(AL)。前节长度(AST)通过ACD与LT之和计算得出。

结果:本研究共纳入早产儿60例60眼,平均经后龄36.80±2.86 wk,其中治疗组30例30眼,对照组30例30眼。治疗组和对照组的平均出生体质量分别为1157.50±232.12和1327.00±432.92 g,平均GA分别为28.46±1.70和30.25±2.12 wk。基线时所有参数均无显著差异(P>0.05)。然而,在矫正GA 3、6和12 mo时,治疗组ACD均显著大于对照组。治疗组LT在3和6 mo时显著变薄,但到12 mo时两组间差异无统计学意义。在整个随访期间,两组间AST、VCD和AL均无显著差异(均P>0.05)。

结论:用于治疗ROP的雷珠单抗仅对ACD和LT产生影响,在出生后第1 a内对AST、VCD和AL未见显著影响。
关键词:雷珠单抗;早产儿视网膜病变;眼部生物测量参数

Abstract

• AIM: To assess the longitudinal changes in ocular biometric parameters after intravitreal ranibizumab (IVR) injection for the treatment of retinopathy of prematurity (ROP) in premature infants during the first year of life.

• METHODS: A longitudinal observational and comparative study was conducted on premature infants diagnosed with type 1 ROP, with a one-year follow-up. In treatment group, patients were administered with ranibizumab injection. The control group was set up without any intervention. All the patients were examined by A-scan ultrasound biometry at 0 (40 gestational wk), 3, 6, and 12 mo of corrected gestational age (GA). Anterior chamber depth (ACD), lens thickness (LT), vitreous chamber depth (VCD), and axial length (AL) were measured. Anterior segment (AST) was calculated by summing up the ACD and LT.

• RESULTS: A total of 60 premature infants (60 eyes) were enrolled in this study, with a mean postmenstrual age of 36.80±2.86 wk, including 30 cases (30 eyes) in the treatment group and 30 cases (30 eyes) in the control group. The mean birth weight was 1157.50±232.12 and 1327.00±432.92 g, and the mean GA was 28.46±1.70 and 30.25±2.12 wk in treatment and control groups, respectively. No significant differences were found in all parameters at baseline (P>0.05). However, after correcting GA by 3, 6, and 12 mo, ACD was significantly greater than that of the control group at the 3rd, 6th, and 12th mo. LT was significantly thinner in the treatment group at the 3rd and 6th mo, but no statistically significant difference was observed between the two groups by the 12th mo. Throughout the follow-up period, AST, VCD, and AL were no significant differences in two groups (all P>0.05).

• CONCLUSION: Ranibizumab administered for the treatment of ROP only affected on ACD and LT. No significant effects are observed on AST, VCD, and AL during the first year of life.

• KEYWORDS: ranibizumab; retinopathy of prematurity; ocular biometric parameter
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INTRODUCTION

Retinopathy of prematurity (ROP) is a retinal vasoproliferative disease and a common cause of visual disability and blindness in children[1-5]. The survival of very premature infants has improved with advances in neonatal care, nevertheless, the incidence of ROP is also increasing[6-7]. The main mechanism of ROP is the release of vascular endothelial growth factor (VEGF) from the avascular retina[8-9]. VEGF causes abnormal vascularization, eventually leading to tractional retinal detachment[10-11]. One approach to treating ROP is by intravitreal anti-VEGF therapy inhibits VEGF activity. The clinical use of anti-VEGF agents for the treatment of ROP has increased worldwide in recent years[12-13]. Ranibizumab (Lucentis, Genentech Inc, Novartis, USA) is the first approved anti-VEGF agent for the treatment of ROP with therapeutic efficacy demonstrated to be superior to laser therapy[14-15]. Currently widely adopted in the global management of ROP, anti-VEGF therapy has become a mainstay of treatment. Numerous studies have suggested that intravitreal ranibizumab (IVR) injection has no significant adverse effects on preterm infants[16-17]. However, most research has focused on its short-term efficacy and research on topics such as retinal vascularization, elevation of intraocular pressure, and systemic adverse events as primary outcomes[18-19].The long-term effects of ranibizumab on ocular health, as well as its potential influence after anti-VEGF therapy, remain unverified. In particular, few follow-up observations have been conducted on the impact of IVR treatment on the ocular biological parameters of premature infants, especially during the first year of life. Given that biometric assessments are crucial for evaluating eye development and refractive status in infants, this lack of data is significant. Consequently, guidelines for the long-term ophthalmologic follow-up of preterm infants after IVR injection have yet to be established.

This study investigated the effects of IVR injection administered for the treatment of ROP on ocular biometric parameters during thefirst year of life in premature infants.

PARTICIPANTS AND METHODS

Ethical Approval This study was approved by the ethics committee of the Northwest Women's and Children's Hospital (ethics number. L2024-089) and was conducted in accordance with the Declaration of Helsinki. Informed consent was waived because of the retrospective and anonymous nature of this study.

Participants This was a single-center, retrospective consecutive case series. We evaluated 60 eyes out of the 5 000 premature infants (GA<37 wk) screened for ROP in the Northwest Women and Children's Hospital, Xi'an, China, from October 1, 2017, to August 31, 2022. Because of the high correlation between the right and left eyes[20], we included only the right eye as the study subject. The study included a 12-month follow-up period, during which assessments were performed at corrected ages of 0 (40 wk), 3, 6, and 12 mo post-ranibizumab treatment. The patients were divided into two groups: treatment group and control group. Inclusion and exclusion criteria were as follows.

Inclusion criteria: All the premature infants gestational age (GA)<37 wk and diagnosed as type 1 ROP[21-22]. For treatment group who received IVR injections as single treatment and no patient required a second dose of IVR due to recurrence of ROP or any other treatment. For control group who did not require any treatment and intervention.

Exclusion criteria: patients with congenital retinopathy, such as familial exudative vitreoretinopathy, Coat's disease, or persistent hyperplastic primary vitreous, were excluded.

Type 1 ROP[23] was defined based on the Early Treatment for Retinopathy of Prematurity study as zone I with any stage with plus disease, zone I with stage 3 without plus disease, or zone II with stage 2 or 3 and plus disease

According the International Classification of Retinopathy of Prematurity, Third Edition. Preterm infants diagnosed withtype 1 ROP are recommended to receive prompt intervention. For Zone I ROP, posterior Zone II ROP, and aggressive-ROP (A-ROP), anti-VEGF therapy is the preferred first-line treatment. Although the disease risks and treatment necessities were thoroughly explained to the guardians, and the majority consented to treatment, a small subset of parents declined intervention due to concerns about surgical risks and the fragile systemic condition of their premature infants. Consequently, these cases were managed with close observation and follow-up.

All patients underwent portable slit-lamp examination, RetCam3 (Clarity Medical Systems, CA, USA), A-scan ultrasound biometry (Topcon, Tokyo, Japan) was performed during the 1-year follow-up.

IVR Injection All treatments were performed by one ophthalmologist. The injections were performed in an operating theater under inhalation anesthesia using an ether mask. After standard aseptic procedures and insertion of an eyelid speculum, the eye was administered with one drop of 0.5% proparacaine, which was allowed to dry. Then, 5% povidone iodine was applied to the ocular surface of the treated eye for 30 s and subsequently washed with sterile normal saline. IVR (Lucentis; 10 mg/1 mL flacon) at a dose of 0.25 mg/0.025 mL was injected 1 mm into the superior temporal corneal limbus using a 30-gauge needle.

Biometry All biological measurements were performed by the same experienced technicians. A-scan ultrasound biometry (Topcon, Tokyo, Japan) was performed at 0 (40 gestational wk), 3, 6, and 12 mo of corrected age. Growth parameters, including GA, birth weight (BW), and postmenstrual age (PMA), were recorded at each time point. Screening for ROP was performed following the guidelines recommended by the Royal College of Paediatrics and Child Health and the Royal

College of Ophthalmologists, United Kingdom. Ultrasonography is widely used for clinical examinations of infants because it is safe and noninvasive. The parameters measured were anterior chamber depth (ACD), lens thickness (LT), vitreous chamber depth (VCD) and axial length (AL). Anterior segment (AST) was obtained as the sum of ACD and LT.

Statistical Analysis Statistical analysis was performed using SPSS statistical software version 23.0 (IBM Corp, Armonk, NY, USA). Since the data were not normally distributed, the Mann-Whitney *U* test was performed for analysis. Accounting for the influence of the differences in GA between the two groups ($P=0.001$). Analysis of covariance (ANCOVA) were used to control for potential confounders such as GA. *P* values <0.05 were considered to be statistically significant.

RESULTS

Sixty premature infants (60 eyes) were enrolled in this study. No significant systemic complications and seriousocular complications, such as cataracts, endophthalmitis, or retinal detachment, were observed after intravitreal injection. The BW did not differ significantly between the two groups ($P=0.065$), but a significant difference in GA was observed ($P=0.001$). To account for the significant difference in GA between the treatment and control groups, we performed an analysis of covariance (ANCOVA) to adjust the data. In the treatment group, the mean±standard deviation GA was 28.46±1.70 wk (range: 26.0-33.5 wk), the BW was 1157.50±232.12 g (range: 850-1720 g), and the PMA at intravitreal injection was 36.80±2.86 wk (range: 32-39 wk). For the control group, the GA was 30.25±2.12 wk (range: 26.0-34.3 wk), and the BW was 1327.00±432.92 g (range: 700-2150 g). The basic patient data are shown in Table 1.

No significant differences were observed in any of the ocular biometric parameters at baseline between the two groups ($P>0.05$). However, it was found that in the treatment group, ACD was significantly greater than that of the control group at the 3rd, 6th, and 12th mo. Meanwhile, LT was significantly thinner in the treatment group at the 3rd and 6th mo, but no statistically significant difference was observed between the two groups by the 12th mo. The mean values of all the biometric parameters at each time point of measurement are shown in Table 2.

DISCUSSION

This study is the first report on longitudinal changes in ocular biometric parameters after IVR injection for the treatment of ROP in premature infants during the 1st year of life. Eye

Table 1 Demographic data of the study group

Groups	Cases (*n*)	Sex (M/F)	GA ($\bar{x}\pm s$, wk)	BW ($\bar{x}\pm s$, g)	PMA ($\bar{x}\pm s$, mo)
Treatment group	30	17/13	28.46±1.70	1157.50±232.12	36.80±2.86
Control group	30	17/13	30.25±2.12	1327.00±432.92	-
P	-	-	0.001	0.065	-

GA: Gestational age; PMA: Postmenstrual age at the time of treatment; BW: Birth weight.

Table 2 The mean values of the biometric parameters between two groups

Parameters	CA (mo)	Treatment group	Control group	*P*
ACD ($\bar{x}\pm s$, mm)	0	2.01±0.04	2.02±0.04	0.786
	3	2.50±0.04	2.26±0.04	0.001
	6	2.72±0.07	2.42±0.07	0.006
	12	2.92±0.07	2.56±0.07	0.002
LT ($\bar{x}\pm s$, mm)	0	3.98±0.03	3.96±0.03	0.636
	3	3.93±0.05	4.12±0.05	0.012
	6	3.91±0.05	4.19±0.05	0.000
	12	4.01±0.07	4.20±0.07	0.076
AST ($\bar{x}\pm s$, mm)	0	5.97±0.05	5.97±0.05	0.961
	3	6.43±0.06	6.39±0.06	0.596
	6	6.63±0.07	6.61±0.07	0.804
	12	6.93±0.09	6.76±0.09	0.206
VCD ($\bar{x}\pm s$, mm)	0	10.85±0.09	10.75±0.09	0.459
	3	11.89±0.11	12.15±0.11	0.114
	6	12.68±0.12	12.87±0.12	0.260
	12	13.55±0.18	13.49±0.18	0.829
AL ($\bar{x}\pm s$, mm)	0	16.84±0.11	16.71±0.11	0.426
	3	18.37±0.13	18.54±0.13	0.386
	6	19.37±0.13	19.49±0.13	0.517
	12	20.43±0.14	20.28±0.14	0.487

CA: Correction age at the time of measurement; ACD: Anterior chamber depth; LT: Lens thickness; AST: Anterior segment; VCD: Vitreous chamber depth; AL: Axial length.

development in premature infants after IVR injection demonstrated consecutive changes in ACD and LT. We found no significant differences between the two groups in all the biometric parameters at 0 mo, probably because IVR does not suppress systemic VEGF concentrations in the 1st wk after injection[24]. Interestingly, the developmental patterns of the ocular components observed in our study differed from those reported in the previous studies. In the treatment group, LT decreased, whereas ACD increased after 3th mo post-treatment, with statistical significance ($P < 0.05$). We speculate that this discrepancy may be associated with the abnormal expression of VEGF in ROP. Previous studies[25-27] have suggested that abnormal VEGF expression in the retina of children may stimulate the development of the ciliary body and lens, which causes the relaxation of the suspensory ligament, aggravates lens hypoxia, and stimulates the proliferation of lens epithelial cells. Therefore ROP causes suspensory ligament dysfunction, shallow ACD and thickened lens. Some other experts[28-30], when tracking the refractive status of children with ROP, also confirmed that patients with a history of threshold ROP are more likely to a shallower anterior chamber, and greater LT. In our study, untreated control group premature infants with ROP exhibited persistent vascular abnormalities, which may lead to structural alterations such as anterior chamber shallowing and lens thickening. In contrast, premature infants in the treatment group who received early anti-VEGF therapy demonstrated effective interruption of disease progression, thereby preserving normal ACD and LT. We speculate that anti-VEGF treatment mitigates pathological responses in the ciliary body and retina by suppressing VEGF expression thus maintaining AST architecture. Alternatively, this discrepancy might stem from limitations in sampling or statistical power. Thus, our proposed mechanism remains speculative and requires further validation.

There were no significant effects on AL, VCD, and AST between two groups in our study. Which is consistent with most previous studies[31-32]. Lin and Tsai[33] studied 25 eyes of 13 patients with threshold ROP who received one dose of IVR treatment after 1 y and also found no significant differences in AL between those who received IVR and those who received bevacizumab after 1 y of follow-up. Lee *et al*[34] compared the effects between laser and intravitreal bevacizumab (IVB) treatment of type 1 ROP and found that the IVB-treated eyes had higher ACD and similar AL. Özdemir *et al*[35] conducted a longitudinal study of infants between 32 and 52 wk' PMA with or without ROP. AL, ACD, and LT were measured by A-scan. They found that at stage 3/3+ ROP, ACD increased from 32 to 52 wk, whereas LT decreased or showed no significant change with GA. This is very similar with our results.

Some studies presented results that contradicted ours. Gunay *et al*[36] compared ocular biometric outcomes following IVB treatment for ROP and compared these results with spontaneously regressed ROP at adjusted 1 y of age. They found that AL and ACD did not differ significantly between the treatment and control groups, whereas LT (3.74 mm) was thicker in the IVB group. This difference in findings may be related to the differences in the basic information of the patients. In their study, the BW and GA were smaller than ours, and the sample size ($n=35$) was also relatively smaller ($n=60$). Furthermore, we chose IVR for treatment, which does not penetrate the retina, has a shorter half-life, is much less systemically toxic, and has a higher general safety profile[24]. Vujanovic*et al*[37] compared 9-month-old premature infants with severe ROP treated with anti-VEGF and laser treatment. The treatment group had significantly higher LT and lower ACD than the control group ($P<0.01$), this differences with us largely because of the differences in the control groups. Many studies have indicated that laser treatment of premature infants result in lower eyeball biometric parameters[26]. Cheng *et al*[2] found that children 4-6 y of age with a history of IVR treatment for type 1 ROP had significantly lower AL. However, in our study, AL was not affected.

Limitations Our study is the first report that show a statistically differences in ACD and LT values on longitudinal changes after IVR injection for the treatment of ROP. At present, we are unsure how the changed occurred after injection IVR in the treatment group. This interpretation remains preliminary and warrants further validation through larger-scale studies. Our study has some limitations, the follow-up time was not long enough, just observed effects on the ocular biometric parameters after intravitreal IVR injection for the treatment of ROP in premature infants during the first year of life and a long-term observation is needed. In addition, this study included a relatively small number of patients. Studies with a larger sample size are needed to confirm our findings.

In conclusion, IVR injections administered for ROP during the 1st year of life in premature infants only affected ACD and LT. No significant effects were observed on the other ocular biological parameters (AL, VCD, and AST).

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Availability of Data and Materials: The datasets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

Authors' Contributions: Study conception and design (Yang J, Zhang L); Data collection (Wang Q, Li CH); Statistical analysis (Yang J); Manuscript writing (Yang J); Critical revision of manuscript (Yang J, Zhang L); Final approval (all authors).

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