• Clinical Research •

Factors influencing the treatment duration and visual prognosis of cytomegalovirus retinitis after allogeneic hematopoietic stem cell transplantation

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Received: 2025-01-12 Accepted: 2025-12-13

Abstract

● **AIM:** To explore the factors influencing the treatment duration and visual prognosis of cytomegalovirus (CMV) retinitis (CMVR) after allogeneic hematopoietic stem cell transplantation (allo-HSCT).

● **METHODS:** All participants received ganciclovir intravenous infusion or oral and intravitreal injection of ganciclovir (IVG) 3 mg twice a week for 4 consecutive times (induction phase). The affected eyes were divided into stop treatment group (Group A), continue treatment group (Group B), and relapse after treatment group (Group C) according to whether local therapy could be terminated at the end of the induction phase and whether CMVR recurred within 3mo after the termination of local therapy.

● **RESULTS:** The study included 31 participants (48 eyes) diagnosed with CMVR including 11 males and 20 females. The mean age was (28±8.2)y. There were 17 cases of binocular disease (34 eyes) and 14 cases of monocular disease (14 eyes). Visual acuity improved in 26 eyes (54.1%), remained unchanged in 9 eyes (18.8%), and decreased in 13 eyes (27.1%). The peak value of blood CMV in Group B was significantly higher than that in Group A (P=0.013). The number of eyes with anterior chamber inflammation in Group C was significantly lower than that in Groups A and B (P=0.015, P=0.016). The average number of interval days was higher in Group A than in Group B. For Group A, there was a strong positive correlation between the number of eyes with CMV positive blood (r=0.712, P=0.031) and visual acuity changes. For Group B, there was a moderately strong positive correlation between the days of blood CMV after transplantation (r=0.371, P=0.043) and the times of injections. For Group C, there was a strong positive correlation between the peak value of blood CMV (r=0.719, P=0.029) and the times of injection.

● **CONCLUSION:** Systemic use of antivirals combined with intravitreal injection of antivirals is effective for patients with CMVR after allo-HSCT surgery. Patients with shorter interval days, higher peak or more days of blood CMV need more injections. Patients with positive blood CMV at initial diagnosis have worse visual prognosis.

● **KEYWORDS:** cytomegalovirus retinitis; allogeneic hematopoietic stem cell transplantation; treatment duration; visual prognosis

DOI:10.18240/ijo.2026.03.13

Citation: Wu S, Ding YH, Zhang C, Hou J. Factors influencing the treatment duration and visual prognosis of cytomegalovirus retinitis after allogeneic hematopoietic stem cell transplantation. *Int J Ophthalmol* 2026;19(3):526-531

INTRODUCTION

Cytomegalovirus retinitis (CMVR) typically manifests in individuals with profound immunosuppression[1], including those diagnosed with acquired immunodeficiency syndrome[2-3], organ transplant recipients[4], or individuals undergoing potent immunosuppressive therapy. In such cases, latent cytomegalovirus (CMV) can reactivate and lead to the development of CMVR[5-6]. In individuals undergoing allogeneic hematopoietic stem cell transplantation (allo-HSCT), the prevalence of CMVR is approximately 5%[7]. The majority of cases manifest within the initial 3mo post-transplantation[8]. If left untreated, CMVR can result in extensive retinal tissue damage and irreversible vision impairment, rendering it the primary cause of blindness in this patient population[9].

CMVR commonly manifests as dispersed yellowish white necrotizing retinal lesions, frequently accompanied by mild

inflammation in the vitreous and anterior chamber[10-12]. However, the initial symptoms of CMVR are typically mild and the efficacy of systemic and intravitreal antiviral therapy is limited, posing significant challenges in the diagnosis and treatment of this condition[13-14]. The present efficacious therapies for CMVR encompass intravenous and intravitreal administrations of ganciclovir[15-16] and foscarnet[17], intravenous cidofovir, and oral valganciclovir[18-19]. Currently, there is no standardized consensus or guideline on the treatment and follow-up of CMVR after allo-HSCT surgery[20]. The purpose of this study is to analyze the clinical and laboratory factors that may affect the treatment duration and vision prognosis of CMVR patients after allo-HSCT surgery at their initial diagnosis, so as to predict and formulate treatment plans for clinicians and coordinate clinical work among departments. And provide a reliable basis for informing patients about the expected course of treatment.

PARTICIPANTS AND METHODS

Ethical Approval People's Hospital of Peking University Ethics Committee (2020PHB158-01) granted the following Ethics approval. Written informed consent was obtained from all individual participants included in the study.

Participants The study included 31 patients (48 eyes) diagnosed with CMVR in the Ophthalmology Department of Peking University People's Hospital from February 2016 to April 2022, including 11 males and 20 females. The mean age was 28±8.2y. There were 17 cases of binocular disease (34 eyes) and 14 cases of monocular disease (14 eyes).

Inclusion criteria: 1) Patients had received allo-HSCT within the past year; 2) Three manifestations of CMVR were found in ophthalmic examination; 3) Aqueous humor test confirmed CMV deoxyribonucleic acid (DNA) load ≥1.0×10 copy/mL; 4) Serum antibody to human immunodeficiency virus was negative; 5) The follow-up period was at least 3mo. Exclusion criteria: 1) The presence of other diseases that can affect visual function (congenital glaucoma, congenital keratopathy, congenital macular disease, *etc*.) and the history of inner eye surgery; 2) Patients with acquired immunodeficiency syndrome.

Withdrawal criteria: 1) Patients voluntarily request withdrawal due to personal factors during the study; 2) Patients can no longer be treated and followed up according to the study method due to the deterioration of their systemic condition during the study; 3) Serious ocular complications (massive vitreous hemorrhage, retinal detachment, infectious endophthalmitis, *etc*.) occurred during the study and required surgical treatment; 4) The occurrence of unknown adverse events that are unacceptable in nature, severity and/or duration, or the occurrence of known unacceptable adverse events that occur more frequently than expected.

Methods All patients received ganciclovir intravenous infusion or oral and intravitreal injection of ganciclovir (IVG) 3 mg twice a week for 4 consecutive times (induction phase). 0.1 mL of aqueous humor was extracted from the patient's eyes one day before the first intravitreal injection (baseline), and CMV DNA load was detected. The level of interleukin-8 (IL-8) was detected by Luminex method, and blood samples were collected to determine the DNA load of CMV. IVG was continued once a week if CMV DNA load in aqueous humor decreased by 2 orders of magnitude or IL-8 level decreased by 1 order of magnitude at the fourth infusion compared to baseline. Otherwise, switch to weekly intravitreal injections of ganciclovir combined with foscarnet. Starting from the fifth intravitreal injection (maintenance phase), 0.1 mL aqueous humor was extracted at the same time of injection each time, and CMV DNA load and IL-8 level were monitored. If CMV DNA load turns negative (<1.0×10 copy/mL) or IL-8 levels less than 30 pg/mL terminated local ocular therapy. All patients were treated with 5 mL of ordinary vacuum blood vessel sampling before each infusion.

According to whether local therapy could be terminated at the end of the induction phase and whether CMVR recurred within 3mo after the termination of local therapy, 48 affected eyes were divided into stop treatment group (Group A), continue treatment group (Group B), and relapse after treatment group (Group C). Ganciclovir intravenous infusion or oral administration should be discontinued if CMV DNA load becomes negative at the end of local treatment, otherwise medication should continue until CMV DNA load becomes negative. Follow up every 2wk for at least 3mo thereafter. The study recorded the best corrected visual acuity and intraocular pressure (IOP) using a Goldmann tonometer, as well as conducting anterior segment and fundus examinations with slit-lamp biomicroscopy and ultra-wide-angle fundus photography. The study involved quantifying the number of quadrants and assessing macular involvement, followed by a comparison of clinical and laboratory data among Groups A, B, and C to identify statistically significant quantitative factors.

Statistical Analysis Statistical analyses were conducted using SPSS version 25.0. The Kolmogorov-Smirnov method is employed to assess the adherence of quantitative data to a normal distribution. An independent samples *t*-test was utilized to perform between-group comparisons for Group A and Group B, Group B and Group C, and Group A and Group C. Following a test for homogeneity of variances, the least significant difference method was employed for significance testing at a threshold of less than 0.05. The Pearson correlation analysis method was employed to assess the association between various parameters, including visual acuity changes

Table 1 Comparison among different groups of clinical data

Clinical data	Group A	Group B	Group C	P^a	P^b	P^c
Eye count	9	30	9	-	-	-
CMV DNA load	32082.33±30269.20	211322.37±443471.86	31338.67±64436.00	0.104	0.99	0.113
IL-8	206.77±212.57	427.83±507.17	405.68±626.37	0.245	0.397	0.907
Baseline IOP	14.78±1.99	16.67±3.99	15.33±3.61	0.179	0.748	0.34
No. of eyes with anterior chamber inflammation	7	20	2	0.534	0.015	0.016
Cumulative number of quadrants	2.22±1.39	2.43±1.17	2.78±1.09	0.645	0.33	0.453
Cumulative macular eye count	4	12	4	0.819	1	0.819
Baseline blood CMV positive eye count	2	5	0	0.982	-	-
Blood CMV days after transplantation	111.67±99.76	66.97±30.83	64±21.68	0.525	0.48	0.984
Blood CMV peak	24611.11±9102.67	71787.67±82146.96	37722.22±34879.92	0.013	0.662	0.226
No. of injections	4±0	7.87±2.3	6.56±2.01	0.000	0.015	0.313
Visual change	0.022±0.22	-0.033±0.24	0.00±0.65	0.891	1.000	0.998

Group A: Stop treatment group; Group B: Continue treatment group; Group C: Relapse after treatment group. [a]Group A *vs* Group B; [b]Group A *vs* Group C; [c]Group B *vs* Group C. CMV DNA: Cytomegalovirus deoxyribonucleic acid; IL-8: Interleukin-8; IOP: Intraocular pressure; CMV: Cytomegalovirus.

and the number of injections, with the resulting correlation coefficient reported. All *P*-values were derived from two-sided tests, with statistical significance defined as $P<0.05$.

RESULTS

Basic Clinical Data The diagnosis of CMVR in 31 patients occurred between 87 and 342d after allo-HSCT, with a median time of 142d. The initial aqueous humor CMV DNA load was detected when aqueous humor was first sampled for detection. The initial IL-8 level of aqueous humor was detected by Luminex method when aqueous humor was extracted for the first time. The interval was the time between allo-HSCT surgery and CMVR diagnosis. Visual acuity change=postoperative visual acuity–preoperative visual acuity (logMAR visual acuity chart). Before each injection, 5 mL of ordinary vacuum blood vessel was used to detect CMV DNA load after blood collection.

Comparison of Clinical Data Among Groups A, B, and C In the 48 eyes, visual acuity exhibited improvement in 54.1% of cases, remained unchanged in 18.8% of cases, and decreased in 27.1% of cases following treatment. There were 9 eyes in Group A (9/48, 18.8%), 30 eyes in group B (30/48, 62.5%), and 9 eyes in Group C (9/48, 18.8%), as shown in Table 1. There were no significant differences (not statistically significant) among Groups A, B and C in initial aqueous humor CMV DNA load, initial aqueous humor IL-8 level, injection times, days of blood CMV after transplantation, baseline IOP, number of blood CMV positive eyes, number of cumulative quadrants, and number of macular involvement. The peak value of blood CMV in Group B was significantly higher than that in Group A (P=0.013), indicating that patients with high peak value of blood CMV needed more intravitreal injection times. The number of eyes with anterior chamber inflammation in Group C was significantly lower than that in Groups A and B (P=0.015, P=0.016), indicating that CMVR patients with anterior chamber inflammation did not mean

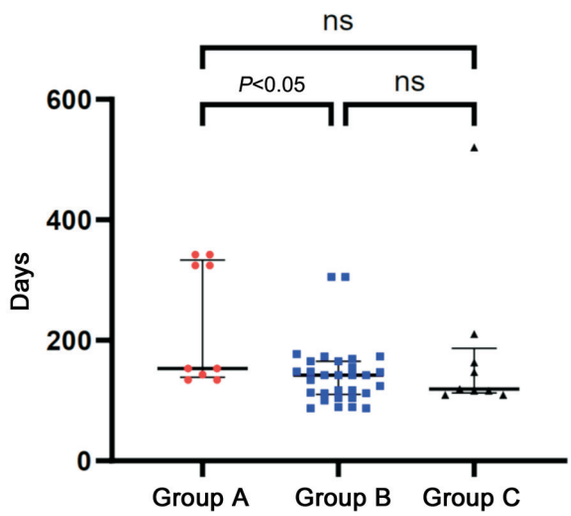

Figure 1 Comparison of interval time in Group A, B and C ns: Not significant.

recurrence. One-way analysis of variance was used to compare the interval between transplantation and CMVR diagnosis among Groups A, B and C, and the results showed that the average number of interval days was higher in Group A than in Group B, indicating that patients with a shorter interval from transplantation to CMVR diagnosis needed more injection times (Figure 1).

Correlation Analysis of Visual Acuity Changes, Injection Times and Influencing Factors in Groups A, B and C For Groups A, B and C, correlation analysis was used to explore the key factors affecting the visual acuity changes and injection times of patients in the group, as shown in Table 2. Since the injection times in Group A were all 4 times, the correlation between this parameter and other variables could not be calculated. For Group A, there was a strong positive correlation between the number of eyes with CMV positive blood at baseline (r=0.712, P=0.031) and visual acuity changes, indicating that patients with CMV positive blood at the first diagnosis had worse visual acuity prognosis. For Group B,

Table 2 Correlation between the times of injection, visual acuity changes and other clinical data in Groups A, B and C

Clinical data	Group A (*n*=9)		Group B (*n*=30)				Group C (*n*=9)			
	Visual change		Interval time		Visual change		Interval time		Visual change	
	r	*P*	*r*	*P*	*r*	*P*	*r*	*P*	*r*	*P*
CMV DNA	-0.756	0.018	-0.165	0.383	0.188	0.32	0.121	0.756	-0.087	0.824
IL-8	-0.178	0.647	-0.035	0.853	-0.031	0.869	0.393	0.295	-0.322	0.399
No. of injections	-	-	-	-	-0.07	0.713	-	-	-0.855	0.003
Baseline vision	0.319	0.403	-0.036	0.849	-0.087	0.648	-0.222	0.566	0.083	0.831
Terminal vision	0.642	0.062	-0.06	0.752	0.277	0.139	-0.724	0.027	0.725	0.027
Visual change	-	-	-0.07	0.713	-	-	-0.855	0.003	-	-
Baseline IOP	0.623	0.073	-0.137	0.472	0.281	0.133	0.161	0.679	-0.241	0.533
Baseline blood CMV positive eye count	0.712	0.031	0.053	0.782	0.012	0.948	-	-	-	-
Cumulative number of quadrants	-0.68	0.044	0.164	0.387	0.187	0.322	-0.621	0.075	0.459	0.214
Cumulative macular eye count	0.207	0.594	-0.319	0.086	0.000	1.000	0.617	0.077	-0.476	0.196
No. of eyes with anterior chamber inflammation	0.465	0.207	-0.459	0.011	0.01	0.959	0.298	0.436	0.000	1.000
Interval time	-0.215	0.579	0.142	0.454	-0.049	0.796	-0.322	0.398	-0.164	0.674
Blood CMV days after transplantation	-0.742	0.022	0.371	0.043	0.035	0.853	0.325	0.394	-0.686	0.041
Blood CMV peak	-0.589	0.095	0.197	0.297	0.306	0.1	0.719	0.029	-0.781	0.013

Group A: Stop treatment group; Group B: Continue treatment group; Group C: Relapse after treatment group; CMV DNA: Cytomegalovirus deoxyribonucleic acid; IL-8: Interleukin-8; IOP: Intraocular pressure; CMV: Cytomegalovirus.

there was a moderately strong positive correlation between the days of blood CMV after transplantation (r=0.371, P=0.043) and the times of injections, indicating that patients with more days of blood CMV after transplantation needed more times of infusion. The other features had no significant correlation with visual acuity change in Group B. For Group C, there was a strong positive correlation between the peak value of blood CMV (r=0.719, P=0.029) and the times of injection, indicating that the higher the peak value of blood CMV, the more times of injection.

DISCUSSION

Prognostic Factors of Vision This study observed that after receiving regular treatment, the visual acuity of 48 eyes improved by 54%, remained unchanged in 19% of patients, and decreased in 27% of patients, indicating that our treatment plan is effective. The results of Wagle *et al*'s[21] study in the previous literature showed that only 16% of CMVR patients after solid organ transplantation had improved vision after treatment. The results of Kuo *et al*'s[22] study showed that the rate of vision loss to 20/50 or worse and 20/200 or worse in non-HIV-infected CMVR patients was 17% and 14%, respectively. The findings of Zhang *et al*'s[23] study indicated that the visual acuity of 24 out of 35 eyes with CMVR after hematopoietic stem cell transplantation (HSCT) surgery either remained stable or showed improvement. The results of Crippa *et al*'s[24] study showed that 75% of patients with CMVR after HSCT had improved their condition. Jeon and Lee[25] showed that all non-human immunodeficiency virus-infected CMVR patients maintained or improved their vision after treatment. The reasons for this difference are incompletely elucidated, and it may be related to the underlying patient population, differences in antiviral prophylaxis treatment strategies, and differences in individual immunosuppressive status[26]. Mota *et al*'s[27] study showed that anti-CMV therapy could significantly change the vision of CMVR patients after HSCT surgery. However, Miao *et al*'s[28] study showed that anti-CMV therapy did not improve the vision of CMVR patients after HSCT surgery. This may be due to permanent damage to photoreceptors early in CMVR and a small sample size.

Shi *et al*'s[9] study on 25 affected eyes suggested that 6 ocular clinical features (macular involvement, optic disc involvement, vitreous opacity, retinal vasculitis, initial visual acuity, and lesion range) could explain 47.5% of the final visual acuity changes, in which macular involvement and initial visual acuity had significant effects on final visual acuity. Macular involvement and initial visual acuity are two important predictors of final visual acuity prognosis in CMVR after HSCT. However, this study suggests that the prognosis of vision is not affected by macular involvement, which may be because the main targets of human CMV in the eye are glial cells, microvascular endothelial cells and retinal pigment epithelium cells, rather than cone and rod cells.

The results of this study showed that the initial aqueous fluid CMV DNA load, the initial aqueous fluid IL-8 level, the number of days of blood CMV after transplantation, baseline IOP, the number of cumulative quadrants, the number of macula involved, and whether or not there was an active inflammatory response in the anterior segment did not affect the visual prognosis, but the patients with positive blood CMV at the initial diagnosis had a worse visual prognosis.

Factors Influencing the Duration of Treatment There is no clear standard for the length of treatment for CMVR patients. In this study, the treatment regimen for allo-HSCT patients complicated with CMVR after surgery was IVG 3 mg, the induction period was twice/week, and the treatment was maintained once/week after 2wk, with a median of 7 times of infusion. Zhang *et al*'s[23] treatment plan was the same as in this study, and the median number of injection times was 6. Jeon and Lee[25] treated 15 patients with 23 eyes human immunodeficiency virus -negative CMVR with IVG 2 mg, the induction period was twice/week, and the therapy was changed to once/week when the lesions stopped progressing. The median infusion of this regimen was 10 times. These results suggest that dose and indicators of the end of the induction phase may influence the number of doses.

Before the intraocular fluid detection technology was applied to the clinic, the treatment endpoint was determined only by the changes of fundus lesions. The intraocular fluid detection technology made the aqueous humor CMV DNA and IL-8 negative, which could also be used as a reference for stopping treatment[29]. A study by Wang found that the CMV DNA load and IL-8 level in aqueous humor of CMVR patients after IVG were significantly reduced, and Kendall correlation test found a strong correlation between the CMV DNA load and IL-8 level in aqueous humor[25]. Another study reviewed the course of treatment in 40 HIV-negative CMVR eyes and found that aqueous humor CMV DNA load was significantly correlated with IL-8 levels. There was no CMVR recurrence in patients with 30 pg/L as the end point of treatment[29]. Zhang *et al*[23] further conducted a prospective randomized controlled study in which 2 groups of CMVR patients received the same IVG treatment after HSCT, and 1 group was converted negative with aqueous humor CMV DNA or IL-8<30 pg/L was used as the end point of treatment, while the other group only used the negative conversion of aqueous humor CMV DNA as the end point of treatment. It was found that the median number of injection times was reduced by 2 times after the introduction of aqueous humor IL-8 as the reference basis, and there were no statistically significant differences in the recurrence rate, complication rate and visual acuity changes between the two groups at half a year follow-up[23]. Among the patients with relapse in this study, two patients adjusted the dosage of glucocorticoids or immunosuppressants before stopping treatment due to changes in systemic conditions, indicating that the aqueous humor CMV DNA load turned negative (<1.0×10 copy/mL) or IL-8 levels less than 30 pg/mL are not considered as treatment endpoints, and the criteria for discontinuation of treatment need to be determined by large-scale prospective studies.

Miao and Hou[30] found that the combination of anterior chamber active inflammatory response and intraocular hypertension at the time of diagnosis of CMVR could be used as important clinical signs to predict the treatment duration of patients. This study found that the ocular conditions of patients were as follows: Initial aqueous humor CMV DNA load, initial aqueous humor IL-8 level, baseline IOP, baseline blood CMV positive eyes, cumulative quadrants number, macular number involved, and whether or not anterior chamber active inflammatory response were combined did not affect the number of vitreous injection times and treatment duration. However, the patient's systemic condition has an impact on the duration of treatment: Patients with a short interval between transplantation and CMVR diagnosis require more vitreous body injection times, which may be related to the lower immunity of patients with a short interval. Ophthalmologists should know the specific transplantation time of patients when they first diagnose CMVR patients, so as to make follow-up treatment plans. Patients with higher blood CMV peak value and more days of blood CMV after allo-HSCT require more intravitreal injection times and longer treatment. Even though IVG can inhibit the replication of intraocular CMV DNA, patients with larger peak blood CMV and more days of blood CMV need more intravitreal injection times and longer treatment time. CMV in the blood can still enter the eye to replicate by disrupting the blood-retinal barrier, resulting in prolonged treatment time. This also serves as a reminder that ophthalmologists treating patients with CMVR should consider not only the ocular manifestations of the disease, but also the systemic implications, including monitoring blood CMV levels in order to develop a personalized treatment strategy.

The main limitation of this study is the small sample size included, which may affect the reliability of statistical analysis. In the future, with the gradual expansion of the sample size and the further extension of the follow-up time, the reliability of the result analysis will be stronger, and even predict the visual change of patients after treatment.

In summary, systematic use of antiviral drugs combined with intravitreal injection of antiviral drugs is safe and effective for patients with CMVR after allo-HSCT surgery. For newly diagnosed patients, in addition to understanding the patient's eye manifestations, the ophthalmologist also needs to understand the patient's general condition. The shorter the interval from transplantation to CMVR diagnosis, the higher the peak value of blood CMV, or the more days of blood CMV, the patients often need more than 4 intravitreal injections therapy. Patients with positive blood CMV at the initial diagnosis have worse vision prognosis, and the combination of anterior ganglion inflammation does not mean that CMVR will recur. When ophthalmologists clinically receive relevant

patients, the conditions should be explained to the patient to low the patient's expectations and ease their anxiety.

ACKNOWLEDGEMENTS

Conflicts of Interest: Wu S, None; **Ding YH,** None; **Zhang C,** None; **Hou J,** None.

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