Predictors of short-term outcomes related to central subfield foveal thickness after intravitreal bevacizumab for macular edema due to central retinal vein occlusion

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Abstract

· AIM: To investigate the predictive factors for short-term effects of intravitreal bevacizumab injections on central subfield foveal thickness (CSFT) in patients with macular edema (ME) secondary to central retinal vein occlusion (CRVO).
· METHODS: This was a retrospective study in 60 eyes treated with intravitreal bevacizumab injections for ME due to CRVO. Follow-up was three months. The Early Treatment Diabetic Retinopathy Study (ETDRS) score and CSFT measured by spectral-domain optical coherence tomography (SD-OCT) were used to observe the changes in best-corrected visual acuity (BCVA). Baseline BCVA, CSFT, age, CRVO duration and the presence of cystoid macular edema (CME) or subretinal fluid (SRF) were analyzed as potential predictive factors of the effects of intravitreal bevacizumab injections.
· RESULTS: BCVA improved from 0.9 logMAR at baseline to 0.6 logMAR at 3mo, which was associated with a significant reduction in CSFT from 721 μm to 392 μm 3mo after injection. About 50% of CME cases and more than 90% of SRF cases responded to treatment with a complete resolution at 3mo. Age (P=0.036) and low baseline CSFT (P=0.037) were associated with a good 3-month prognosis. Patients >60 years old achieved better CME resolution (P=0.031) and lower CSFT at 3mo (305 μm vs 474 μm, P=0.003).
· CONCLUSION: Intravitreal bevacizumab significantly improved visual acuity and CSFT in patients with CRVO after 3mo. Older age and lower baseline CSFT were good predictors of short-term CSFT outcomes. The retinal thickness response to bevacizumab might depend on the resolution of CME rather than SRF.

· KEYWORDS: central retinal vein; bevacizumab; macular edema; intravitreal injection; central subfield foveal thickness

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INTRODUCTION

Central retinal vein occlusion (CRVO) is a common vascular disease of the retina that often leads to severe vision loss due to macular edema (ME) [1]. Pathologically, CRVO often leads to increased retinal thickness, cystoid macular edema (CME) and subretinal fluid (SRF) because of the disruption of the blood-retinal barrier [2]. The age- and gender-standardized prevalence of CRVO is estimated to be 0.80 per 1000 individuals [3]. Risk factors include hypertension, age, diabetes, glaucoma, high intraocular pressure, high blood viscosity, cerebrovascular diseases and cardiovascular diseases [3]. Therapeutic options for ME include focal laser photocoagulation [4], intravitreal steroids [5] and surgery [6]. However, some of these options are still controversial. Several studies have shown the efficacy of intravitreal injections of anti-vascular endothelial growth factor (VEGF) compounds such as bevacizumab, pegaptanib and ranibizumab [7-11]. VEGF levels are increased in the vitreous fluid of patients with CRVO and are positively correlated with retinal thickness, suggesting that VEGF plays an important part in the pathological process of CRVO [12-13]. Therefore, anti-VEGF agents were tried and were proven to be efficient in reducing ME and improving visual acuity (VA) [7,11,14-15]. However, not all patients benefit from anti-VEGF therapy. Some studies have indicated that the elimination of the thickening resulting from ME can improve the VA [16-17], but that the resolution of foveal thickness was incomplete or late in some patients. Several studies observed that age, duration of symptoms, baseline central subfield foveal thickness...
(CSFT), and presence of CME or SRF could be potential predictors for VA, but their conclusions remain unclear [18-20]. Moreover, little is known about the predictors for the outcomes of retinal thickness after anti-VEGF treatments. A recent study have shown that after 3mo of ranibizumab, optical coherence tomography (OCT) images provided predictive information for patients with CRVO [18]. Therefore, the purpose of the present study was to investigate the efficacy and the potential predictors of short-term (3-month) outcomes related to CSFT measured by OCT after intravitreal injection of bevacizumab in patients with CRVO.

SUBJECTS AND METHODS

Subjects This was a retrospective study performed in 60 Chinese Han patients (60 eyes), who received at least one injection of 1.25 mg of bevacizumab intravitreally for ME due to CRVO at the Beijing University Eye Center, Beijing University Third Hospital, Beijing, China, between May 2012 and May 2014. Inclusion criteria were: 1) ME due to CRVO involving the fovea; 2) minimal pretreatment CSFT of $\geqslant 320 \mu m$; 3) fluorescein angiography-confirmed non-ischemic CRVO (<10 disc diameter of non-perfusion in CRVO [21]); 4) treatment-naive; 5) follow-up of at least 3mo post-treatment. Exclusion criteria were: 1) previous treatments such as laser coagulation, intravitreal injection or retinal surgery; or 2) neovascularization or other retinal diseases at baseline. The present study was approved by the Institutional Review Board of the Beijing University Third Hospital. This study adheres to the tenets of the Declaration of Helsinki. Informed consent was obtained after patients were informed about the nature and possible risks of the study and with special note of the off-label use of bevacizumab.

Examination Baseline examination included a best-corrected visual acuity (BCVA) testing using the Early Treatment Diabetic Retinopathy Study (ETDRS) chart, intraocular pressure measured by the Goldman method, slit-lamp biomicroscopy, color fundus photography, spectral-domain OCT (SD-OCT; Spectralis-OCT, Heidelberg Engineering, Heidelberg, Germany), and fluorescein angiography. CRVO was diagnosed by fundus photography and fluorescein angiography ([ff450, Carl Zeiss GmbH, Oberkochen, Germany]). BCVA results were converted to the logarithm of the minimum angle of resolution (logMAR) values. The average of all points within the inner circle of 1-mm radius was defined as the CSFT, which was calculated as the distance between the vitreoretinal interface and the retinal pigment epithelial-Bruch's membrane complex through the foveal area [22]. The presence of CME and SRF was also evaluated.

Study Treatment The eyes were anesthetized with 1% tetracaine eye drops. Intravitreal injections of bevacizumab (1.25 mg in 0.05 mL, Genentech, Inc., San Francisco, CA, USA) were administered under sterile conditions using a 30-gauge needle 3.5 mm posterior to the limbus, through the inferotemporal pars plana. Antibiotic drops (levofloxacin, Santen Pharmaceutical Co., Osaka, Japan) were given for 3d before and after the injection.

Study Follow-up and Observational Indexes After a single intravitreal injection of bevacizumab, the effects were evaluated monthly using BCVA and CSFT determined by SD-OCT for 3mo. Additional injections were given for recurrent or persistent ME. In our center, there is no algorithm for administration of bevacizumab; instead, bevacizumab injection is based on OCT results. Data were interpreted at baseline, 1 and 3mo. Data collected included age, gender, CRVO duration, baseline BCVA, baseline CSFT, number of intravitreal injections, history of diabetes mellitus or arterial hypertension, and the presence of CME or SRF. The main outcomes of this study were changes in BCVA and CSFT measured by SD-OCT. A secondary outcome measure was the resolution of the CME and SRF. Complications and side effects were noted. Patients with CRVO were divided into two subgroups according to treatment response at 3mo based on SD-OCT: responders (CSFT $< 320 \mu m$, response group) and late or incomplete responders (CSFT $\geqslant 320 \mu m$, incomplete response group). This threshold was based on a previous study suggesting a threshold of $< 315 \mu m$ for normal CSFT when using SD-OCT [20]. A threshold of $< 320 \mu m$ was used in the present study to be even more conservative.

Statistical Analysis Statistical analysis was performed using SPSS 17.0 (SPSS Inc, Chicago, IL, USA). Data are expressed as means $\pm$ standard deviation (SD). Multivariate analysis was performed using a logistic regression model using the CSFT response as the outcome variable. Potential predictors tested in the multivariate model were BCVA, baseline CSFT, age, duration of the CRVO, and the presence of CME or SRF. Comparisons of baseline and final characteristics between the two groups were performed using the Chi-square test for categorical variables and the Student's $t$-test for continuous variables. Follow-up and baseline data were compared using the paired $t$-test. Correlations were tested using the Pearson correlation coefficient. $P$-values $<0.05$ were considered statistically significant.

RESULTS

Demographics and Baseline Characteristics Baseline characteristics of the patients are shown in Table 1. Figures 1 and 2 present two typical cases. Sixty eyes (60 patients; 28 males and 32 females) with ME due to CRVO were included in the analysis. Mean age was 58.14 $\pm$16.58y (range: 13 to 86). CRVO was of the non-ischemic type in all patients. Duration of symptoms was 15.40 $\pm$23.47wk (range: 1 to 144). The average number of
injectionswas1.80 ± 0.60. Arterialhypertension was
found in 20 patients anddiabetes in 12. Ten patients had
arterial hypertension and diabetes. At baseline, the mean
VA was 0.897 ± 0.395 logMAR and the mean CSFT was
721.2 ± 180.8 μm. All patients had CME at baseline. Among
them, 36 patients (60%) had CME alone and 24 patients
(40%) had SRF.

 Except for age (responders: 62.33 ± 16.77 years, incomplete
responders: 48.64 ± 15.73 years, P = 0.04), there were no differences
between the two groups for any baseline characteristic (all
P > 0.05).

Response to Treatment Table 2 presents the changes in
eye parameters after bevacizumab treatment in all patients.
Mean CSFT decreased from 721.2 ± 180.8 μm to 392.3 ±
180.9 μm (P < 0.001) 1mo after treatment, and remained stable
at 3mo (392.1 ± 185.4 μm, P < 0.001 vs baseline). Meanwhile,
BCVA improved from 0.897 ± 0.395 logMAR to
0.616 ± 0.350 logMAR (P < 0.001) at 1mo, and remained
stable at 3mo (0.616 ± 0.360 logMAR, P < 0.001 vs baseline).

Table 2 Changes in eye parameters after intravitrealbevacizumab
injections in patients with ME secondary to CRVO n (%)

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Baseline</th>
<th>1mo</th>
<th>3mo</th>
</tr>
</thead>
<tbody>
<tr>
<td>BCVA (logMAR)</td>
<td>0.897±0.395</td>
<td>0.616±0.350b</td>
<td>0.616±0.360b</td>
</tr>
<tr>
<td>CSFT (μm)</td>
<td>721.2±180.8</td>
<td>392.3±180.9b</td>
<td>392.1±185.4b</td>
</tr>
<tr>
<td>Complete resolution of ME</td>
<td>0</td>
<td>32/60 (53.3)</td>
<td>34/60 (56.7)</td>
</tr>
<tr>
<td>Presence of CME alone</td>
<td>36/60 (60.0)</td>
<td>25/60 (41.7)a</td>
<td>25/60 (41.7)a</td>
</tr>
<tr>
<td>Presence of CME+SRF</td>
<td>24/60 (40.0)</td>
<td>3/60 (5.0)a</td>
<td>1/60 (1.7)a</td>
</tr>
</tbody>
</table>

aP<0.05 vs baseline; bP<0.01 vs baseline; BCVA: Best-corrected visual acuity; logMAR: Logarithm of the minimum angle of
resolution; CSFT: Central subfield foveal thickness; ME: Macular edema; CME: Cystoid macular edema; SRF: Subretinal fluid.
The frequency of CME and SRF decreased from 40% at baseline to 5% at 1mo ($P=0.005$) and to 1.7% at 3mo ($P<0.001$ vs baseline, $P=0.308$ vs 1mo). Baseline CME correlated with baseline CSFT ($r=0.573$, $P<0.001$), and the improvement of VA was correlated with the decrease in CSFT ($r=0.405$, $P=0.002$).

No cases of endophthalmitis, retinal detachment or any other severe procedure-related complications were observed. No patient developed neovascular complications or systemic adverse events during follow-up.

**Comparison Between Responders and Non-responders**

Table 3 presents the comparison of the outcomes between the two groups. BCVA was improved in both groups (responders: $-0.327±0.330$ logMAR, $P<0.001$; incomplete responders: $-0.175±0.238$ logMAR, $P<0.001$), but without difference between the two groups ($P=0.051$). CSFT was improved in both groups (responders: $-402.6±185.1$ μm, $P<0.001$; incomplete responders: $-254.9±228.9$ μm, $P<0.001$), and the best improvement was observed among responders ($P<0.001$). However, more patients achieved a complete resolution of ME among responders compared with incomplete responders (93.3% vs 20.0%, $P<0.001$). The frequency of CME alone was lower among responders (67.6% vs 3.3%, $P<0.001$). There was no difference in the frequency of CME and SRF ($P=0.390$).

**Multivariate Analysis**

Age, duration of the disease, baseline BCVA, baseline CSFT and the presence of baseline CME alone or CME and SRF were included in a multivariate analysis using the achievement of a CSFT <320 μm as the dependent variable. Analysis revealed that young age ($P=0.036$) and high CSFT at baseline ($P=0.037$) were associated with a bad 3-month prognosis (Table 4).

**Subgroup Analysis Based on Age**

The subgroup of patients who were older than 60y (34 eyes, 56.7%) revealed a considerable decrease of 408.1 μm in the mean CSFT (from 731.8 μm to 305.1 μm, $P<0.001$). In contrast, patients aged 60y or less (26 eyes, 43.3%) only showed a decrease of 236.7 μm (from 708.2 μm to 474.5 μm, $P<0.01$), and the difference was significant between the two age subgroups ($P=0.003$). Although the initial CSFT was not different ($P=0.308$), the final CSFT in the younger group was significantly worse than in the older group ($P=0.003$). No significant differences regarding duration, baseline VA, presence of CME or SRF were observed. However, CME resolution was better in the older group compared with the younger one (67.6% vs 38.4%, $P=0.031$) (Table 5).

**DISCUSSION**

The aim of the present study was to investigate the predictive factors for short-term outcomes related to CSFT after intravitreal bevacizumab injection in patients with ME secondary to CRVO. Results showed that BCVA was improved at 3mo, and was associated with a significant reduction in CSFT after 3mo. About 50% of CME cases and more than 90% of SRF cases responded to treatment with a complete resolution at 3mo. Age and a low baseline CSFT were associated with a good 3-month prognosis. Patients $\geq$60 years old achieved better CME resolution and lower CSFT at 3mo compared with patients aged $\leq$60y.

Although some studies showed the efficacy of intravitreal injection of anti-VEGF drugs [9-11], the causes for the lack of response in some patients with ME due to CRVO remain unknown [18]. The present study showed that most non-ischemic CRVO patients had an immediate response to bevacizumab injections. Moreover, the early responders (CSFT $<320 \mu m$ at 3mo) achieved better visual improvements.

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### Table 3 Comparison of eye parameters 3mo after bevacizumab treatment between responders and non-responders

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Responders (n=30)</th>
<th>Incomplete responders (n=30)</th>
<th>$P$</th>
</tr>
</thead>
<tbody>
<tr>
<td>BCVA improvement (logMAR)</td>
<td>-0.327±0.330</td>
<td>-0.175±0.238</td>
<td>0.051</td>
</tr>
<tr>
<td><strong>$P$</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CSFT improvement (μm)</td>
<td>-402.6±185.1</td>
<td>-254.9±228.9</td>
<td>0.001</td>
</tr>
<tr>
<td><strong>$P$</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Complete resolution of ME</td>
<td>28/30 (93.3)</td>
<td>6/30 (20.0)</td>
<td>0.001</td>
</tr>
<tr>
<td>Presence of CME alone</td>
<td>2/30 (6.7)</td>
<td>23/30 (76.7)</td>
<td>0.001</td>
</tr>
<tr>
<td>Presence of CME+SRF</td>
<td>0</td>
<td>1/30 (3.3)</td>
<td>0.390</td>
</tr>
</tbody>
</table>

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### Table 4 Multivariate analysis of final CSFT

<table>
<thead>
<tr>
<th>Parameters</th>
<th>OR</th>
<th>95%CI</th>
<th>$P$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>0.960</td>
<td>0.924-0.997</td>
<td>0.036</td>
</tr>
<tr>
<td>Duration</td>
<td>0.986</td>
<td>0.960-1.012</td>
<td>0.282</td>
</tr>
<tr>
<td>Baseline BCVA</td>
<td>1.186</td>
<td>0.927-1.380</td>
<td>0.178</td>
</tr>
<tr>
<td>Baseline CSFT</td>
<td>1.001</td>
<td>0.894-1.281</td>
<td>0.367</td>
</tr>
<tr>
<td>Baseline CME or CME+SRF</td>
<td>0.764</td>
<td>0.205-1.849</td>
<td>0.668</td>
</tr>
</tbody>
</table>

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### Table 5 Multivariate analysis of final CSFT

<table>
<thead>
<tr>
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<th>OR</th>
<th>95%CI</th>
<th>$P$</th>
</tr>
</thead>
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<tr>
<td>Baseline CME or CME+SRF</td>
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<td>0.205-1.849</td>
<td>0.668</td>
</tr>
</tbody>
</table>
than the late or incomplete responders (CSFT ≥ 320 μm at 3mo). Multivariate analysis revealed that patients with favorable response to treatment were older and had lower CSFT at baseline. Thus, the foveal thickness response to bevacizumab may depend on the resolution of CME, rather than the presence of SRF. Patients who were older than 60y achieved better resolution of CME and lower CSFT at 3mo. This is supported by Bhisitkul et al. [18], who observed that early responders to ranibizumab achieved better visual outcomes than late responders, and that early responders had a CSFT of 250 μm or less at baseline; however, they did not observe any effect from age.

In the present study, intravitreal bevacizumab therapy resulted in a significant short-term improvement of the mean VA and a decrease in the mean CSFT at 3mo, which is supported by recent studies[24-25]. The correlation between the improvement of VA and the decrease in CSFT was also observed by Bhisitkul et al. [19]. Furthermore, CME was resolved in 53% of patients after the first injection without recurrence at 3mo, which is supported by studies by DeCroos et al. [26] and Hoeh et al. [27]. In these two previous studies, the response to the first injection was the most important and seemed to be predictive of short-term treatment results[26-27].

Multivariate analysis revealed that patients with favorable retinal thickness response to the treatment were older and had lower CSFT at baseline, whereas baseline VA, duration, and presence of CME or SRF had no predictive value. Only a few studies have examined baseline CSFT as a prognostic factor for OCT treatment outcomes[18-19], but a study reported no significant correlation between baseline CSFT and foveal thickness at the last follow-up [20]. In the present study, lower baseline CSFT was associated with a better response to bevacizumab.

The present study suggested that the early responders (CSFT <320 μm at 3mo) had a tendency to achieve better visual improvements compared with late or incomplete responders (CSFT ≥ 320 μm at 3mo), with better resolution of CME (P<0.001). Some studies have reported that the presence of SRF at baseline did not influence the response to bevacizumab [20,28]. In addition, results of the present study showed that SRF was present at baseline in 40% of patients and disappeared in more than 90% of patients at 3mo in both groups. Noma et al. [29] have suggested that the vitreous levels of VEGF were higher in patients with CRVO and SRF than in those with CME alone, suggesting a greater effect of bevacizumab in these patients. Compared with the negative impact of SRF, the resolution of CME might determine the retinal thickness and VA outcomes. As reported by Bhisitkul et al.[18], patients who had residual CME at 3mo had a worse visual outcome at 6mo. The presence of cystic spaces might be more disruptive to the retinal architecture, predicting that CME would have a negative impact on vision.

Interestingly, in the present study, older patients achieved better resolution of CME and lower CSFT at 3mo. Age has been proven to be a risk factor for retinal vein occlusion [21], and younger age was always predictive of better response for VA outcomes [19,27,30-32]. In addition, some studies have reported that age had no predictive value for VA outcomes [33,34]. Few studies reported the impact of age on foveal thickness outcomes. Ach et al. [19] suggested that the patients who showed better OCT responses were younger, which may be due to generally healthier ocular tissues in younger patients. However, in the present study, younger age might be predictive of late or incomplete response for foveal thickness outcomes. However, these results should be interpreted with caution because of the small subgroup size. As we know, younger patients with CRVO may have greater association with inflammatory conditions compared with older ones [19] because inflammatory cytokines may play an important role [33,36]. Moreover, inflammatory cytokines were more often correlated with morphologic changes assessed by SD-OCT rather than VEGF-A [17]. A more marked decrease in ME in younger patients after intravitreal anti-angiogenic therapy

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Age≤60a</th>
<th>Age&gt;60a</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>26</td>
<td>34</td>
<td></td>
</tr>
<tr>
<td>Duration (wk)</td>
<td>11.88±13.07</td>
<td>18.25±29.27</td>
<td>0.309</td>
</tr>
<tr>
<td>Baseline BCVA (logMAR)</td>
<td>0.839±0.440</td>
<td>0.891±0.360</td>
<td>0.622</td>
</tr>
<tr>
<td>Baseline CSFT (μm)</td>
<td>708.2±235.8</td>
<td>731.8±122.4</td>
<td>0.646</td>
</tr>
<tr>
<td>Presence of CME/CME+SRF</td>
<td>16/10</td>
<td>20/14</td>
<td>0.522</td>
</tr>
<tr>
<td>3-month BCVA (logMAR)</td>
<td>0.623±0.433</td>
<td>0.609±0.294</td>
<td>0.891</td>
</tr>
<tr>
<td>3-month CSFT (μm)</td>
<td>474.6±218.4</td>
<td>305.1±119.9</td>
<td>0.003</td>
</tr>
<tr>
<td>Baseline vs 3-month BCVA (logMAR)</td>
<td>0.216±0.191</td>
<td>0.284±0.361</td>
<td>0.356</td>
</tr>
<tr>
<td>Baseline vs 3-month CSFT (μm)</td>
<td>236.7±233.6</td>
<td>408.1±174.1</td>
<td>0.003</td>
</tr>
<tr>
<td>Resolution of CME</td>
<td>10/26</td>
<td>23/34</td>
<td>0.031</td>
</tr>
</tbody>
</table>

BCVA: Best-corrected visual acuity; logMAR: Logarithm of the minimum angle of resolution; CSFT: Central subfield foveal thickness; ME: Macular edema; CME: Cystoid macular edema; SRF: Subretinal fluid.
was also reported by several studies [20,28,30]. Therefore, VEGF inhibition alone may not be sufficient to decrease the inflammatory response, especially in younger patients with CRVO [27]. Accordingly, addition of an anti-angiogenic agent may be more effective in younger patients.

The present study is not without limitations. First, the sample size was small. Although we could not exclude the effects of the small sample size, the impact of age on the response to retinal thickness outcomes after bevacizumab should be underlined. Second, in spite of the absence of a control group, the retrospective nature of the study was a limitation in itself. In addition, despite the fact that the intervention in our center is based on the Branch Retinal Vein Occlusion: Evaluation of Efficacy and Safety (BRAVO) trial [39], the treatment regimen do not follow a strict treatment algorithm, but is based primarily on OCT-guided therapy, which was reported by previous studies [13,30]. Finally, the follow-up period was not very long (1 and 3mo) because these are the standard post-injection follow-up visits after intravitreal injection of bevacizumab in our center. Therefore, prospective studies with larger sample sizes are necessary to determine factors responsible for the response to bevacizumab in these patients.

In conclusion, the present study suggests that intravitreal bevacizumab injections given by OCT-guided dosing regimen improved VA and CSFT in non-ischemic CRVO patients after 3mo. Lower baseline CSFT and older age were good predictors of short-term CSFT outcomes. Further studies with a larger sample size are necessary to validate these conclusions.

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REFERENCES

Predictors for central subfield foveal thickness after anti-VEGF


