Published in final edited form as:

Retina. 2011 October ; 31(9): 1835–1840. doi:10.1097/IAE.0b013e31821ba2dc.

Predictive Factors for Visual Outcome to Intravitreal Bevacizumab in Young Chinese Patients with Myopic Choroidal Neovascularization

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Abstract

Purpose—To report the anatomical and functional outcomes of intravitreal bevacizumab (IVB) in both young and old Chinese patients with myopic choroidal neovascularization (mCNV).

Methods—Consecutive series of 56 eyes (52 patients) with mCNV treated exclusively with IVB were reviewed retrospectively. Data from clinical examination, fundus photography, fluorescein angiography, and optical coherence tomography were collected.

Results—Higher myopia was positively correlated to a worse outcome ($r=-0.3$; $p=0.036$). Stratifying by age, the correlation between spherical equivalent (SE) and final outcome showed statistical significance ($r=-0.44$, $p=0.027$) only in younger patients. In young patients, both SE ($p=0.036$) and initial visual acuity (VA) ($p=0.004$) were predictive factors for visual outcome after adjusting for age, SE, and number of injections, whereas in older patients, only initial VA ($p<0.0001$) was predictive of visual outcome after similar adjustments.

Conclusion—Young patients did not have a better outcome when compared to older patients. Initial VA, regardless of age, plays a more significant role. Both initial VA and SE are predictive factors for final VA in young Chinese patients.

Keywords

bevacizumab; choroidal neovascularization; Chinese; pathological myopia; young

INTRODUCTION

Pathologic myopia (PM) is the second most common cause of visual impairment in Chinese population.¹ As one of the most sight threatening complications of PM, choroidal neovascularization (CNV) is a common cause of visual loss in untreated patients^{2–6} and the estimated risk of developing myopic CNV (mCNV) is approximately 4–10%.^{7–9} Choroidal ischemia may develop because of this mechanical strain, followed by the atrophy of retinal pigment epithelium (RPE) and overlying retina with subsequent growth factor release.⁸

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Conflict of Interest: No conflicting relationship exists for any author

These changes produce conditions that are conducive to breaks in Bruch's membrane, RPE atrophy, and finally CNV formation.⁴

CNV secondary to PM usually affects a population that is younger, on average, compared with age-related macular degeneration (AMD). Moreover, the disease is less predictable with variable progression.¹⁰ Photodynamic therapy (PDT) with verteporfin has been shown to reduce the risk of visual loss with mCNV at one year after treatment, but two year results were not statistically significant.^{11–15} More than 50% of patients have persistent CNV leakage and 13% developed visual loss of three lines or more at one year post treatment.^{11;12;16}

Recent reports suggest that an anti-angiogenesis agent that blocks vascular endothelial growth factor (VEGF), bevacizumab (Avastin, Genentech Inc, South San Francisco, California, USA), may be a safe and efficacious alternative.^{17–24} Several studies have shown significant improvement of visual acuity (VA) at one year with intravitreal bevacizumab (IVB) treatment.^{22–25} However, the number of young patients (age<50 years) are underrepresented in these studies. This report investigates the effect of IVB on visual outcome and central foveal thickness in patients with mCNV and the correlation between spherical equivalent (SE) and age as a function of visual outcome.

MATERIALS AND METHODS

From January 2007 to December 2009, a total of 56 eyes from 52 patients with mCNV were followed and treated with IVB (1.25mg/0.05ml) at Chang Gung Memorial Hospital, Taiwan. In this retrospective study, patient data were obtained after approval by the institutional review board and signed informed consents from patients were also collected. Inclusion criteria for this study were: (1) refractive error greater than -6.0 diopter (D) and/or axial length longer than 26 mm and characteristic pathologic fundus changes, such as chorioretinal atrophy, lacquer cracks and atrophic patches; (2) active CNV as demonstrated on fluorescein angiography (FA) and optical coherence tomography (OCT) and (3) minimum follow-up of 12 months. The exclusion criteria were: (1) any ocular disease associated with CNV other than PM, such as AMD, idiopathic CNV and angioid streaks; (2) prior treatment with photocoagulation, PDT with verteporfin, sub-tenon triamcinolone acetonide, prior or concurrent treatment with intravitreal injection of ranibizumab; (3) history of prior vitrectomy or intraocular surgery other than cataract surgery and (4) presence of retinal detachment, foveoschisis, drusen or macular hole.

Each patient received a complete ophthalmic examination, including Snellen best corrected visual acuity (BCVA), slit-lamp biomicroscopy, tonometry, fundus examination, FA (Imagenet, Topcon Corporation, Tokyo, Japan) and OCT scanning (Stratus OCT 3, Zeiss Jena GmbH, Jena, Germany). Bevacizumab (1.25mg/0.05ml) was injected into the vitreous cavity at 3.5 mm or 4 mm posterior to the limbus with 30-gauge needle similar to previously described regimen.²⁴ Re-treatment was based on the presence of active leakage on FA, persistent subretinal fluid on OCT or new hemorrhage. VA and central foveal thickness were monitored monthly and documented initially and post injection at 1 month and every 3 months thereafter for statistical analysis. VA was converted to the logarithm of the minimum angle of resolution (logMAR) units for statistical analysis. Statistical evaluation was performed using SPSS (Version 17.0, SPSS Inc., Chicago, IL, USA) and SAS (Version 9.1., SAS Institute Inc., Cary, NC, USA). Paired t-test was performed to determine the effect of visual outcome post treatment. Patients were grouped according to age (age<50 years and age≥50 years) and the differences in visual outcome between the two groups were compared using two sample t-test. In addition, sample t-test was also used to determine the differences in visual outcome of older patients with or without cataract surgery. Pearson's correlation

was performed to determine the relationship between SE and visual outcome. Linear regression was performed to determine the effect of initial VA, age, SE, and number of injections on visual outcome. A p-value of less than 0.05 was considered significant.

RESULTS

There were 56 eyes from 52 patients (37 women and 15 men) included in this study. The mean ($\pm$ standard deviation [SD]) age was 47.63 ($\pm$ 15.37) years (range, 16–80 years) and the mean follow-up time was 17.5 $\pm$ 4.9 months. CNV occurred in 26 right eyes (46.4%) and 30 left eyes (53.6%). The average SE was -11.03 D ($\pm$ 3.79 D). The average number of injections was 2.2 and over half of the eyes (51.8%) achieved resolution with just one injection. There were 25 eyes in patients age <50 years old and 31 eyes in patients age $\geq$ 50 years. Demographic data between the two groups are described in Table 1.

The mean BCVA ($\pm$ [SD]) improved significantly from 1.09 ± 0.71 logMAR at baseline to 0.77 ± 0.78 logMAR at the 12th month ($p < 0.0001$). Mean central foveal thickness decreased significantly from 271 microns (μ m) at baseline to 228 μ m at the 12th month ($p = 0.017$). Paired t-test showed significant improvement in VA at the 1st, 3rd, 6th, 9th, and 12th month compared to baseline ($p = 0.009$ for 1st month and $p < 0.0001$ in subsequent months). The greatest improvement was seen within the first 3 months and VA stabilizes thereafter (Figure 1). Initially, in the first 12 months of follow-up, patients less than 50 years of age appeared to have less VA improvement (mean= 0.28 ± 0.60 , 95% CI= $0.05-0.52$, $p = 0.022$) when compared to patients greater than or equal to 50 years of age (mean= 0.37 ± 0.48 , 95% CI= $0.19-0.55$, $p = 0.0003$). However, further evaluation using linear regression analysis showed that this discrepancy is due to a worse initial VA found in older patients and is not attributed to age. Patients with a worse initial VA had a greater improvement during the first 12 months of follow-up. Therefore, initial VA was the most predictive factor for visual outcome ($p < 0.0001$) after adjusting for age, SE, and number of injections (beta= 0.68). SE was not correlated to the initial VA but is significantly correlated to the final VA ($r = -0.3$; $p = 0.036$) using Pearson's correlation. Higher myopia was positively correlated to a worse outcome (Figure 2). When comparing SE between younger versus older patients, young patients on average were more myopic (-11.45 D) than older patients (-10.73 D). However, the mean difference between the two groups was not statistically significant. Stratifying by age, the correlation between SE and final outcome showed statistical significance only in young patients ($r = -0.44$, $p = 0.027$) whereas the correlation lose statistical significance in older patients ($p = 0.51$). This suggested that SE is also predictive of final VA and that higher myopia relates to a worse visual outcome only in young patients. Further analysis using linear regression confirmed this result. In young patients, both SE ($p = 0.036$) and initial VA ($p = 0.004$) were predictive factors for visual outcome after adjusting for age, SE and number of injections, whereas in older patients, only initial VA ($p < 0.0001$) was predictive of visual outcome after similar adjustments.

In the four patients with bilateral mCNV, two were younger than 50 and two were older than 50. Both bilateral young patients have higher myopia than the mean (-15.25 D versus -11.45 D), while the older patients have previously received cataract surgery. The distinction found in these two groups may suggest a possible difference in the pathogenesis of mCNV between younger and older patients. Finally, older patients who had previously received cataract surgery ($n = 10$ eyes) prior to the development of mCNV showed a worse improvement in VA in the 3rd ($p = 0.032$), 6th ($p = 0.028$), 9th ($p = 0.019$), and 12th ($p = 0.014$) month after treatment when compared to older patients who did not receive surgery ($n = 21$ eyes). No adverse systemic or ocular complications, such as endophthalmitis, retinal detachment, cataract or glaucoma were observed.

DISCUSSION

Intravitreal injection of bevacizumab has become the first-line therapy for the treatment of mCNV.²⁶ In our study, we found that IVB significantly improves patients' vision without ocular or systemic complications. Previous studies have shown that IVB has beneficial results in the treatment of mCNV; however, most of these studies included patients who previously received PDT treatment or focused on much older study subjects. In this study, we aim to elucidate the effect of bevacizumab on mCNV in young Chinese patients without prior or concurrent adjunctive treatments.

The natural course of CNV attributed to PM without any intervention is extremely poor. Yoshida *et al* reported that almost 100% of untreated patients with mCNV had a visual outcome worse than 20/200 in 5–10 years of follow-up²⁷ and the prognosis is highly dependent on age of onset of mCNV.^{28;29} Similarly, visual outcome is also dependent on age of onset in patients with mCNV who received PDT with verteporfin treatment.^{14;15} Visual outcome has been shown to be more favorable in younger (<55 years of age) patients.^{14;15} Ikuno *et al* suggested that the critical age for the prognosis of mCNV may be close to 60 years of age.³⁰ In light of these results, in our study, we chose the age of 50 as the cut-off point to delineate between younger versus older patients who received IVB treatment for mCNV.

This study is unique in that we have the largest young patients with PM who received only IVB without prior or concurrent adjunctive treatments (Table 2). Studies by Chan²² and Ruiz-Moreno²⁵ have patient pools with similar age as our study but they included patients who had previously received PDT treatments (44.8%) in the outcome analysis. As a result, the visual outcome from their studies may not be comparable. Ikuno *et al*²⁴ excluded adjunctive treatments in their study, but the average age of their study was about 10 years older than our study.

A second strength of this present study is that the average age is 47.6 years, almost ten years younger compared to the average age of subjects in previous studies from Japan or Italy. Furthermore, the average age of our young patient subgroup is 34.4 years, almost 20 years younger than previously published data. Gharbiya *et al* divided patients into a younger (<50 years of age; 8 eyes from 8 patients) and an older (≥ 50 years of age; 12 eyes from 12 patients) group and found that visual outcome was statistically better in younger patients ($p=0.03$) whom required less injections ($p=0.003$).²³ However, other reports found no statistical significance.¹⁷ The reason for this discrepancy may have been that the younger patients were underrepresented in these previous studies. Ikuno *et al*³⁰ examined the effect of PDT versus IVB on PM in older Asian women, presumably because there are more older PM patients in Japan. Since the number of young PM patients is more prevalent in Taiwan, the differences shown from our result may be accounted for by ethnic differences.

In Taiwan, the prevalence of myopia is 21%, 61%, and 81% among children ages 7, 12, and 15 respectively, and high myopia ($>-6D$) is seen in 21% of 18 year olds.³¹ Since there is a high prevalence of myopia since childhood in our geographical region, the effect of prolonged state of high myopia in young patients may be more detrimental. Higher SE tends to have more severe chorioretinal degeneration that could result in a worse final VA. It is likely that the retina seen in these patients are more vulnerable to damage because of a more stretched state. Since SE is not correlated to the initial VA, patients with higher SE have a worse prognosis because of more advanced chorioretinal degeneration or poorer response to treatment when compared with patients with lower SE.

In our study, we also compared the outcome of cataract surgery within the older population and found those patients who received cataract surgery had a worse visual outcome at the

3rd, 6th, 9th, and 12th month post IVB treatment when compared to those who did not receive surgery. Of those who did receive surgery, only 1 eye underwent Yttrium Aluminum Garnet (YAG) capsulotomy, suggesting that IVB is less effective in older patients who received cataract surgery and this observation was not attributed to the shortened duration of drug action in the vitreous due to YAG capsulotomy.

Hayashi *et al* found that the rate of CNV in highly myopic eyes after cataract surgery was 12.5%.³² We hypothesize that vitreous liquefaction plays an important role in worsening the visual outcome among our patients who had cataract extraction. Experimental studies have shown that the mechanism of vitreous liquefaction is different in age related degeneration and high myopia.³³ In age- related degeneration, the increase in liquid vitreous was concurrent with a decrease in gel vitreous by a synchronistic fashion. However, in myopic degeneration, there is active synthesis of liquid vitreous, causing a pressure gradient difference between the vitreous and suprachoroidal space. Thus, while there is growing evidence which suggest that vitreous liquefaction and posterior vitreous detachment (PVD) may be beneficial in ischemic retinal diseases, by increasing intravitreal oxygen tension and sustaining anti-VEGF effect,^{34;35} this may not be true for highly myopic old patients after cataract extractions. In these patients, the high ratio of liquid to gel vitreous may be responsible for an early wash-out effect of bevacizumab. These findings collectively suggest a difference in the pathogenesis of mCNV between young and old patients.

There are several limitations to our study. First, the retrospective nature makes standardization of patient treatments and follow up difficult. The variability in the number of injections is largely dependent on the primary physician. Whereas some physicians administer three monthly injections initially,²² others may use the findings of FA as a diagnostic tool for subsequent injections. Even though there is a wide range of variability in the follow-up period for each patient, we limited this confounding factor by investigating the first twelve months of each patient. Finally, even though our sample size of young patients is the largest to date, future studies with even larger sample sizes may be needed to corroborate our significant findings. Nonetheless, this study provides evidence showing that initial visual acuity is the most predictive factor for visual outcome and that spherical equivalent is also correlated to visual outcome, especially in young PM patients.

With the largest sample size of young patients to date, we found that young patients did not have a better outcome compared to older patients. More importantly, initial VA, regardless of age, plays a more significant role. While age may be a beneficial factor in patients who received PDT for mCNV,^{14;15} this effect is not observed in patients who received IVB in the treatment for mCNV. Interestingly, when we stratify by age, both initial VA and SE are predictive factors for final VA in young patients – an observation not seen in older patients. A better initial VA and less myopia result in a more favorable outcome in young patients with mCNV treated with IVB. This may be due to the differences in pathogenesis of mCNV between young and older patients.

Acknowledgments

Financial Support: None

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Figure 1. Changes in Visual Acuity during 12 Month Follow-Up

Graph showing changes in the mean logarithm of the minimum angle of resolution (logMAR) best-corrected visual acuity (BCVA) after intravitreal bevacizumab treatment. Error bar, standard error of the mean. Single asterisk ($p<0.009$) and dagger ($p<0.0001$) indicate significant differences compared to baseline by paired t-test.

Figure 2. Correlation between Spherical Equivalent and Visual Outcome

Figure showing positive correlation between spherical equivalent and visual outcome at the 12th month after intravitreal bevacizumab treatment. Correlation coefficient (r) was measured using Pearson's correlation.

Table 1

Demographic Characteristics between Young versus Old Patients

	Young (<50 years old)	Old (≥50 years old)	Total
	n=25	n=31	n=56
Male:Female	7:16	7:22	14:38
OD:OS	9:16	17:14	26:30
SE (±SD)	-11.45±4.66	-10.73±2.96	-11.03±3.79
No. of Injections	1.88	2.42	2.18
Initial VA (logMAR)	0.94	1.24	1.09
Final VA (log MAR)	0.66	0.87	0.77

Log MAR= Logarithm of the minimum angle of resolution, No=number, OD=right, OS=left, SD=standard deviation, SE=spherical equivalent, VA=visual acuity

Table 2
Comparison of Mean Age Between Studies on Intravitreal Bevacizumab in Pathological Myopia

Author	Year	Ethnicity	No. eyes (pts)	Mean age	Adjunctive Treatments	SE	Baseline (logMAR)	12 month (logMAR)
Chan ²⁵	2009	Chinese	29(29)	48.9±15.3	PDT (44.8%)	-10±3.5	0.62±0.26	0.38±0.31
Charbiya ²⁴	2009	Italian	20(20)	53.1±14.0	PDT (10%)	-9.8±6.83	0.60206	0.243038
Ruiz-Moreno	2009	Spanish	29(28)	50±15	PDT (44.8%)	-13.6±4.3	0.55±0.25	0.38±0.32
		subgroup *	15	-	-	-	0.42±0.21	0.25±0.23
Ikuno ²¹	2009	Japanese	63(63)	58.4±13.6	TA (7.9%)	-11.4 ±4.7	0.57 ± 0.43	0.33 ± 0.34
Hayashi ²³	2009	Japanese	43(43)	56.5±13.8	TA(9.3%), PDT (20.9%), TA+PDT (2.3%)	-14.5±5.1	0.68±0.29	0.45±0.35
Kuo	2010	Chinese	56(52)	47.63±15.37	Excluded	-11.03±3.79	1.09±0.71	0.77±0.78
		subgroup *	25(23)	34.4±9.4	Excluded	-11.45±4.66	0.94±0.56	0.66±0.81

* age<50, -= not available

logMAR= logarithm of the minimum angle of resolution, PDT= photodynamic therapy with verteporfin, pts=patients

SE=spherical equivalent, TA= triamcinolone acetonide