

Single-site Baseline and Short-term Outcomes of Clinical Characteristics and Life Quality Evaluation of Chinese Wet Age-related Macular Degeneration Patients in Routine Clinical Practice

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Abstract

Background: Age-related macular degeneration (AMD) is the leading cause of irreversible vision loss among the older population. In China, treatment of age-related ocular diseases is becoming a priority in eye care services. This study was to investigate the clinical characteristics and quality of life of Chinese patients with wet AMD and current treatment types, to evaluate short-term gains in different treatments, and to investigate associations between visual function and vision-related quality of life (VRQoL).

Methods: A prospective, observational, noninterventional study was conducted. Basic data were collected from patients with clinical diagnoses of wet AMD before clinical assessments at baseline. VRQoL was measured with the Chinese version of the National Eye Institute Visual Function Questionnaire-25 (NEI VFQ-25). Correlations of the NEI VFQ-25 subscale scores with best-corrected visual acuity (BCVA) and between-group differences were analyzed.

Results: A total of 80 wet AMD patients were enrolled, with the mean age of 68.40 years. About one-quarter of wet AMD patients received intravitreal (IVT) ranibizumab treatment, and 67% of them were treated on a *pro re nata* basis. The visual acuity of patients treated with IVT ranibizumab at month 3 after treatment was significantly increased, whereas patients treated with traditional Chinese medicine achieved no significant improvement. Cronbach's α for the NEI VFQ-25 subscales ranged from 0.697 to 0.843. Eight subscale and overall composite scores were moderately correlated with the BCVA of the better-seeing eye. Significant differences in the overall NEI VFQ-25 scores and other subscales were observed between patients with BCVA in the better-seeing eye of less than 50 letters and the others.

Conclusions: Patients treated with IVT ranibizumab experienced better vision improvement at short-term follow-up. The Chinese version of the NEI VFQ-25 is a valid and reliable tool for assessing the VRQoL of Chinese wet AMD patients.

Key words: Chinese Version of National Eye Institute Visual Function Questionnaire-25; Ranibizumab; Vision-related Quality of Life; Wet Age-related Macular Degeneration

INTRODUCTION

Age-related macular degeneration (AMD) is the leading cause of irreversible vision loss and blindness among the older population in most developed countries and some developing countries. In China, with the rapid growth of the aging population, age-related ocular diseases are becoming a priority in eye care services. AMD occurs in dry (also known as atrophic) and wet (also known as neovascular or exudative) forms, which usually results in blurred or distorted vision or even vision loss in the center of the visual field because of damage to the retina.^[1-4] Wet AMD has a

relatively low incidence, but if left untreated, severe visual impairment will occur. According to a previous report, the proportion of untreated wet AMD patients who developed severe vision loss increased from 21.3% at 6 months to 41.9% by 3 years.^[5] Also, some studies showed a correlation between decreased visual function and vision-related quality of life (VRQoL) in AMD patients. In these studies, AMD-related visual impairment included psychological distress and reduction in participation of social events.^[6-10]

The recent development of anti-vascular endothelial growth factor (VEGF) substances for use in ophthalmologic clinical treatments has markedly improved the prognosis of patients with wet AMD. Intravitreal (IVT) anti-VEGF treatments provide vision maintenance in more than 90% of patients and substantial improvement in 25–40% of patients.^[11]

Access this article online

Quick Response Code:



Website:
www.cmj.org

DOI:
10.4103/0366-6999.156083

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Ranibizumab was officially approved for the Chinese market as the first IVT anti-VEGF therapy drug in 2012, and it offered a new treatment choice for Chinese ophthalmologists and AMD patients. We therefore conducted this study in Shanghai, to evaluate the ocular characteristics of wet AMD patients and current treatment strategies in routine clinical practice in China. An additional purpose of this study was to evaluate disease development and the impact of VRQoL in wet AMD patients.

METHODS

Participants

In this prospective, observational, noninterventional study design, the treatment choice was based on the decision of the physician only, regardless of study participation and treatment use. To be eligible for participation, patients were clinically diagnosed as having wet AMD in at least one eye. All patients were asked to follow-up every 3-month, and written informed consent was obtained from all participants. Patients who had received anti-VEGF treatment either systematically or intravitreally within the previous 90 days or who were currently participating in any other interventional study were not eligible.

Clinical assessments

The patients' details included gender, age, educational level, profession, and risk factors such as hypertension, diabetes mellitus, smoking, cardiovascular disease, and history of stroke. Following collection of patients' basic data, a comprehensive ocular assessment was performed including the best-corrected visual acuity (BCVA), dilated fundus examination, and fluorescein angiography detection, as well as optical coherence tomography (OCT) assessment of the macula. Due to the noninterventional approach of the study, the patients were assessed, diagnosed, and treated by retina specialists, and BCVA was measured by trained evaluators.

Best-corrected visual acuity was measured with a 4-m Early Treatment Diabetic Retinopathy Study (ETDRS) backlit lighthouse chart. The central retinal thickness (CRT) was obtained using Heidelberg Spectralis OCT (Heidelberg, German). The angiographic subtype of a patient's lesion was defined in relation to the visualization of choroidal new vessels (classic) in the fluorescein angiogram. The total area of a predominantly classic lesion included more than 50% classic choroidal neovascularization (CNV), the total area of a minimally classic lesion included less than 50% classic CNV, and the total area of an occult lesion included no classic CNV. The greatest linear dimension (GLD) of a lesion, CNV, or leakage was measured on the fluorescein angiogram. Each patient was asked to follow-up at months 3, 6, 9, and 12. At baseline and each follow-up visit, BCVA, CRT, and treatment type were recorded. At baseline and month 12, the Chinese version of the National Eye Institute Visual Function Questionnaire-25 (NEI VFQ-25) was administered.

Vision-related quality of life

Vision-related quality of life was evaluated using the Chinese version of the NEI VFQ-25. The questionnaire was

administered by trained interviewers in a face-to-face interview format and was scored according to the guidelines provided by the instrument developers. The NEI VFQ-25 is composed of 25 questions that address 12 subscales that can be grouped together in three broad categories of subscales. The first category is the general health subscale (1 question), followed by the second category comprised of five subscales, which indicates the quality of vision and includes the general vision (1 question), near vision (3 questions), distance vision (3 questions), peripheral vision (1 question), and color vision (1 question) subscales. The third category is comprised of six subscales that assess the VRQoL: Dependency (3 questions), role limitations (2 questions), mental health (4 questions), social functioning (2 questions), ocular pain (2 questions), and driving (2 questions). The scores in Table 1 range from 0 (worst-possible VRQoL) to 100 (best-possible VRQoL), and a higher score indicates better visual function.

Statistical analysis

Demographic variables and clinical findings were summarized by descriptive analyses. Differences between mean values of multiple groups were analyzed by one-way analysis of variance with least squares deconvolution tests. The significance of the differences between BCVA and CRT of baseline and at 3-month follow-up were assessed using paired *t*-tests. The significance of associations between NEI VFQ-25 subscale scores and visual function was assessed using the Spearman correlation coefficient. A $P < 0.05$ was considered as statistically significant. All computations were performed with SPSS 17.0 (SPSS Inc., USA) software.

RESULTS

Baseline demographic and clinical characteristics

A total of 80 wet AMD patients were enrolled in this single-site study, and 77 patients had completed the first follow-up at month 3. The mean age of the 80 participants was 68.40 years (standard deviation [SD], 9.76 years), and the mean age at AMD onset was 67.55 years (SD, 10.04 years). All participants were Han Chinese. Table 2 shows the demographic and clinical characteristics at the baseline

Table 1: NEI VFQ-25 subscales

Category	Subscale	Number of questions
1-General health (1)	General health	1
2-Quality of vision (9)	General vision	1
	Near vision	3
	Distance vision	3
	Peripheral vision	1
	Color vision	1
3-VRQoL (15)	Dependency	3
	Role limitations	2
	Mental health	4
	Social functioning	2
	Ocular pain	2
	Driving	2

VRQoL: Vision-related quality of life; NEI VFQ-25: National Eye Institute Visual Function Questionnaire-25.

Table 2: Patient's baseline demographic and clinical characteristics

Characteristics	n (%)
Gender	
Female	38 (47.5)
Male	42 (52.5)
Educational level	
Primary school or less	11 (13.8)
Secondary school	46 (57.5)
Tertiary school	23 (28.8)
Distribution	
Urban	73 (91.3)
Rural	7 (8.8)
Profession	
Medical worker	7 (8.8)
Farmer	4 (5.0)
Office-based worker	18 (22.5)
Worker	17 (21.2)
Other	34 (42.5)
Better or worse-seeing eye treated	
Better-seeing eye	16 (20)
Worse-seeing eye	64 (80)
Angiography lesion criteria	
Predominantly classic	29 (36.7)
Minimally classic	30 (38.0)
Occult with no classic	20 (25.3)
Treatment type (baseline/month 3)	
Ranibizumab IVT	21/6 (26.3/7.8)
Monthly injection	7 (7.5)
PRN	14 (18.8)
TCM	41/43 (51.3/55.8)
PDT	2/0 (2.5/0)
Observation	16/28 (20.0/36.4)

TCM: Traditional Chinese medicine; PDT: Photodynamic therapy; IVT: Intravitreal; PRN: *Pro re nata*.

visit. Only one patient failed to finish the angiography because of an allergy. The fluorescein angiogram results showed that most cases were minimally classic, followed by predominantly classic, and occult with no classic. The mean GLD, represented by the lesion size of wet AMD in the studied eye was 3276.58 μm (SD, 2890.46 μm). Twenty-one participants received 0.5 mg ranibizumab IVT, among which seven patients received monthly therapy, whereas the other 14 patients were treated on a *pro re nata* (PRN) basis after the first IVT administration. Forty-one patients received oral traditional Chinese medicine (TCM) therapy at baseline, and two more changed to TCM at month 3. Photodynamic therapy (PDT) was suggested for only two patients, whereas the remaining 16 patients were asked to follow-up without any interventional treatments.

Risk factors

More than 40% of the participants had hypertension; only four patients were diagnosed with diabetes and received treatments. Approximately, one-third of the enrolled participants were cigarette smokers, and Table 3 shows the smoking index (years of smoking \times number of cigarettes per day).

Best-corrected visual acuity

The mean BCVA of all patients at baseline was 33.45 letters (SD, 24.24 letters), and no differences were found among the four subgroups that received different treatment types. The mean BCVA at month 3 follow-up was 34.17 letters (SD, 23.75 letters), and patients who received ranibizumab IVT and PDT achieved significant BCVA improvement among the four subgroups [Table 4]. The mean BCVA increased from 45.00 (SD, 22.88) to 52.23 (SD, 22.17) letters in patients treated PRN based on OCT, whereas the monthly therapy group improved by about 11 letters (27.86 \pm 18.45 to 38.43 \pm 17.23). No significant difference was obtained between the two subgroups at baseline or month 3 ($P > 0.05$ each). No difference was observed between the BCVA of the TCM-treated and observation groups.

Central retinal thickness

Optical coherence tomography measurements were available for each patient at baseline and the month 3 visit. The mean CRT at baseline for all patients was 492.44 μm (SD, 280.27 μm) and decreased to 476.31 μm (SD, 282.60 μm) at month 3. The improvement in BCVA in IVT ranibizumab-treated patients was associated with CRT, which showed a significant reduction from baseline to the 3-month follow-up [Table 4].

National Eye Institute Visual Function Questionnaire-25 scores and correlations with best-corrected visual acuity

As shown in Table 5, the subscale completion rate was 100%, except for the driving score ($n = 5$), because there are few elderly drivers in China. With the exception of vision-specific dependency (Cronbach's $\alpha = 0.697$), the subscales demonstrated a moderately strong internal consistency and reliability, with Cronbach's α ranging from 0.711 to 0.834. As the response rate of the driving subscale was rather low in the present population, the Cronbach's α was increased to a range of 0.869 to 0.912 when the driving subscale was omitted.

The general vision, near vision, distance vision, peripheral vision, vision-related dependency, role limitations, mental health, social functioning, and overall composite scores were moderately correlated with the BCVA of the better-seeing eye. Better visual function scores were associated with higher scores on the overall NEI VFQ-25. This relation was exhibited for subgroups on the basis of both the better-seeing and worse-seeing eyes, but the association was stronger when the better-seeing eye visual function results were used [Table 6].

National Eye Institute Visual Function Questionnaire-25 scores by best-corrected visual acuity letters

Except for the subscales of general health, color vision, and ocular pain, significant differences in the overall NEI VFQ-25 scores and other subscales were observed among the three subgroups: Better-seeing eye with a BCVA less than 50 letters (subgroup A, $n = 13$), 51–69 letters (subgroup B, $n = 28$), and more than 70 letters (subgroup C, $n = 39$). The

driving subscale was omitted because the completion rate was rather low for comparison [Figure 1 and Tables 7,8].

DISCUSSION

According to a report from the Beijing Eye Study, 2.0% and 7.7% of low vision and blindness cases, respectively are caused by AMD in China.^[12] Zou *et al.* reported that the prevalence of AMD in Shanghai residents over 50 years old is 15.5%, and that of wet AMD is 1.79%.^[13] In this observational study focused on wet AMD, most of the participants were from Shanghai and had a relatively higher education level in the elderly population. The classifying type of CNV was based on fluorescein angiogram in our study, and we found that 38% of these patients were minimally classic, followed by predominantly classic, and occult, which is similar to the

results of a previously reported VISION study^[14] but differs from the results of the WAVE study in Germany.^[15] It was reported that increased risks for wet AMD were associated with moderate to severe hypertension, cigarette smoking, higher levels of serum cholesterol, and cardiovascular disease.^[16,17] In our study, more than 40% of the enrolled participants had definite hypertension and history of anti-hypertensive medication administration, and 28.8% were currently smoking cigarettes. Our results indicate that hypertension and smoking are likely the two greatest risk factors for wet AMD in the elderly Chinese population.

In China, anti-VEGF therapy, PDT, and TCM are currently the most common interventional treatments for wet AMD in routine clinic practice, and ranibizumab is now the only labeled IVT medicine for wet AMD. As shown in two major clinical trials, the comparison of Age-related Macular Degeneration Treatments Trials and the alternative treatments to inhibit VEGF in age-related choroidal neovascularization study, which compared continuous versus either PRN or discontinuous anti-VEGF IVT therapy, individualized treatments based predominantly on OCT decreased the mean number of injections, while the outcomes were similar.^[18,19] In our study, 21 patients received one IVT ranibizumab treatment at baseline, 14 of whom were then treated as needed. Patients treated by PDT and TCM did not achieve a significant increase in ocular functions, which were represented by BCVA scores. However, we cannot ignore the fact that the cost of IVT ranibizumab must be borne by patients and caregivers in China. This financial burden may have limited some patients' choices or even doctors' choices, especially when patients need multiple injections.

With progressive damage to the macula, AMD patients will experience a multitude of visual problems that significantly affect their mental health and quality of life. Given the importance of adding VRQoL assessments into medical practice and the increasing prevalence of AMD in today's aging population, it is critical to understand the impact of AMD on VRQoL and to accomplish the measurement of VRQoL in routine ophthalmologic practice.^[20] The NEI VFQ-25 was found to be the most commonly used psychometric tool to evaluate the VRQoL,^[21] and it has been validated in patients with wet AMD in the United States¹⁰. The Chinese version of the NEI VFQ-25 was also shown to be a valid and reliable instrument to measure VRQoL in Chinese patients with visual impairment.^[22-24] The subscale scores of distance

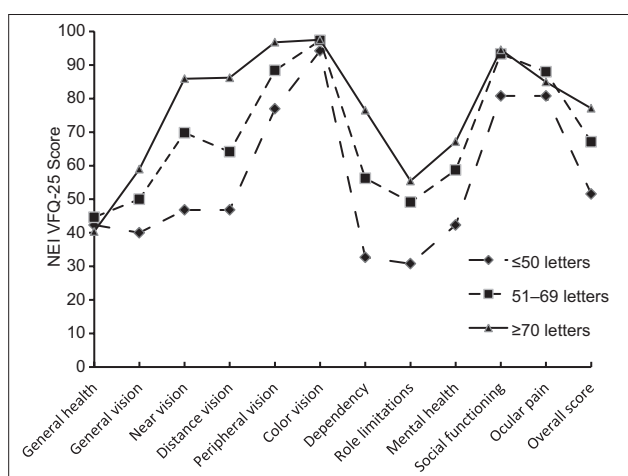


Figure 1: National Eye Institute Visual Function Questionnaire-25 overall and subscale scores by best-corrected visual acuity (BCVA) letters. The BCVA of the better-seeing eye was divided into three subgroups: Less than 50 letters ($n = 13$), 51–69 letters ($n = 28$), and more than 70 letters ($n = 39$).

Table 3: Risk factors for wet AMD		
Risk factors	n (%)	History of onset/smoking index (mean \pm SD)
Hypertension	33 (41.2)	13.00 \pm 10.51
Diabetic	4 (5.0)	8.75 \pm 5.32
Stroke	2 (2.5)	6.00 \pm 5.66
Cardiovascular disease	5 (6.2)	7.20 \pm 4.32
Smoking	23 (28.8)	501.61 \pm 434.24

SD: Standard deviation; AMD: Age-related macular degeneration.

Table 4: Analysis of BCVA and CRT changes between baseline and M3 follow-up				
Viabes	Ranibizumab	TCM	PDT	Observation
Baseline BCVA (letters, mean \pm SD)	39.292 \pm 2.61	30.85 \pm 24.10	24.50 \pm 26.16	33.56 \pm 27.27
Baseline CRT (μ m, mean \pm SD)	475.00 \pm 232.16	497.44 \pm 276.39	668.00 \pm 158.39	480.56 \pm 362.89
M3 BCVA (letters, mean \pm SD)	47.40 \pm 21.21	29.62 \pm 23.51	26.00 \pm 26.87	29.75 \pm 22.88
M3 CRT (μ m, mean \pm SD)	402.80 \pm 210.59	494.33 \pm 273.30	598.50 \pm 82.73	487.12 \pm 363.35
P (baseline to M3 BCVA)	0.008	0.165	0.205	0.088
P (baseline to M3 CRT)	0.007	0.632	0.418	0.691

M3: Month 3; BCVA: Best-corrected visual acuity; CRT: Central retinal thickness; SD: Standard deviation; TCM: Traditional Chinese medicine; PDT: Photodynamic therapy.

Table 5: Scores and internal consistency reliability (Cronbach's α) of NEI VFQ-25 subscales

NEI VFQ-25 subscale	<i>n</i>	Score (mean \pm SD)	Cronbach's α	Cronbach's α without driving subscale
General health	80	42.19 \pm 20.12	NA	NA
General vision	80	52.75 \pm 14.67	NA	NA
Near vision	80	73.91 \pm 25.66	0.715	0.872
Distance vision	80	72.08 \pm 27.82	0.711	0.870
Peripheral vision	80	90.62 \pm 15.08	NA	NA
Color vision	80	97.50 \pm 8.53	NA	NA
Dependency	80	62.29 \pm 27.74	0.697	0.869
Role limitations	80	49.22 \pm 25.34	0.834	0.879
Mental health	80	60.16 \pm 20.32	0.726	0.881
Social functioning	80	91.88 \pm 15.03	0.808	0.894
Ocular pain	80	85.31 \pm 14.99	0.762	0.912
Driving	5	73.33 \pm 6.97	0.811	NA
Overall composite score	80	69.44 \pm 16.55	NA	NA

NA: Not applicable; SD: Standard deviation; NEI VFQ-25: National Eye Institute Visual Function Questionnaire-25.

Table 6: Correlations between NEI VFQ-25 subscale scores and BCVA

NEI VFQ-25 subscale	Spearman rank-order correlation coefficient (<i>r</i>)			
	Better-seeing eye BCVA (letters)	<i>P</i>	Worse-seeing eye BCVA (letters)	<i>P</i>
General health	-0.011	0.923	0.130	0.249
General vision	0.563	0.000	0.218	0.052
Near vision	0.552	0.000	0.292	0.009
Distance vision	0.523	0.000	0.303	0.006
Peripheral vision	0.448	0.000	0.358	0.001
Color vision	0.155	0.169	0.082	0.469
Dependency	0.568	0.000	0.240	0.032
Role limitations	0.452	0.001	0.095	0.403
Mental health	0.496	0.000	0.147	0.193
Social functioning	0.231	0.039	0.272	0.015
Ocular pain	0.021	0.853	0.016	0.888
Driving	0.211	0.734	0.222	0.720
Overall composite score	0.550	0.000	0.280	0.012

NEI VFQ-25: National Eye Institute Visual Function Questionnaire-25; BCVA: Best-corrected visual acuity.

vision, dependency, role limitations, and mental health among participants in the present study were lower than those from the field testing of NEI VFQ-25 scores among subnormal subjects.^[22] Cronbach's α coefficient is commonly used to assess internal consistency and reliability; a value of 0.70 or greater indicates acceptable internal consistency reliability. The Chinese version of the NEI VFQ-25 used in this study had a high internal consistency coefficient for overall and all subscales (Cronbach's $\alpha > 0.8$) when the driving subscale was omitted. A previous study found that the BCVA of the better-seeing eye was the major determinant of VRQoL.^[25] In our study, the correlations of VFQ-25 subscale scores with

Table 7: Comparisons of NEI VFQ-25 scores by BCVA subgroup

NEI VFQ-25 subscale	<i>P</i> value for comparison of subgroup A with B	<i>P</i> value for comparison of subgroup A with C	<i>P</i> value for comparison of subgroup B with C
General health	0.733	0.768	0.399
General vision	0.025	0.000	0.007
Near vision	0.002	0.000	0.004
Distance vision	0.032	0.000	0.000
Peripheral vision	0.013	0.000	0.014
Color vision	0.282	0.103	0.509
Dependency	0.003	0.000	0.001
Role limitations	0.026	0.002	0.292
Mental health	0.010	0.000	0.070
Social functioning	0.011	0.004	0.727
Ocular pain	0.157	0.388	0.420
Overall composite score	0.001	0.000	0.005

NEI VFQ-25: National Eye Institute Visual Function Questionnaire-25; BCVA: Best-corrected visual acuity.

Table 8: National Eye Institute Visual Function Questionnaire-25 overall and subscale scores by best-corrected visual acuity (BCVA) letters

NEI VFQ-25 subscale	≤ 50 letters	51-69 letters	≥ 70 letters
General health	42.31	44.64	40.38
General vision	40	50	58.97
Near vision	46.8	69.79	85.9
Distance vision	46.8	64.14	86.22
Peripheral vision	76.92	88.39	96.79
Color vision	94.23	97.32	97.5
Dependency	32.69	56.25	76.5
Role limitations	30.77	49.11	55.45
Mental health	42.31	58.7	67.15
Social functioning	80.77	93.3	94.55
Ocular pain	80.77	87.95	84.94
Overall score	51.57	67.08	77.09

The BCVA of the better-seeing eye was divided into three subgroups: Less than 50 letters (*n* = 13), 51-69 letters (*n* = 28), and more than 70 letters (*n* = 39) NEI VFQ-25: National Eye Institute Visual Function Questionnaire-25.

better-seeing eye BCVA were more significant than those with worse-seeing eye BCVA, and patients with a better-seeing eye BCVA more than 60 letters achieved significantly elevated scores for the overall composite score and all subscales.

One limitation of the current study is that visual function was represented only by BCVA. Other clinical measurements, such as contrast sensitivity and reading speed, are also complementary to visual acuity in some aspects that affect quality of life,^[20] and thus, it would strengthen our conclusion if these clinical measurements were included. In addition, the response rate for the driving subscale was only 6.25% in our study. It has been demonstrated in some studies that the driving subscale has poor construct validity and reliability,^[26,27] and most older adults in China do not drive, especially when they

suffer from impaired vision. Therefore, the driving subscale was not very practicable among Chinese AMD patients, which indicates that further adjustment is needed in future studies.

In conclusion, the baseline and short-term follow-up results from this observational, noninterventional study suggest that about one-quarter of wet AMD patients in China receive anti-VEGF IVT treatment in routine clinical practice, and two-thirds of them were treated PRN guided by OCT measurements. IVT ranibizumab helps wet AMD patients obtain a greater increase in visual function than TCM. The Chinese version of the NEI VFQ-25 is a valid and reliable tool for assessing the visual function and life quality of Chinese patients with wet AMD. Wet AMD patients with damaged vision have lower VRQoL, which was related to the better-seeing eye BCVA, especially when the BCVA of the better-seeing eye was less than 50 ETDRS letters. However, this single-site study in Shanghai cannot represent the entire population in China, and studies of larger samples across multiple centers are needed. Longitudinal follow-up is now undergoing, and the results may aid assessments of the impact of different treatments on the VRQoL of wet AMD patients.

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Received: 26-11-2014 **Edited by:** Li-Shao Guo

How to cite this article: Wang LL, Liu WJ, Liu HY, Xu X. Single-site Baseline and Short-term Outcomes of Clinical Characteristics and Life Quality Evaluation of Chinese Wet Age-related Macular Degeneration Patients in Routine Clinical Practice. *Chin Med J* 2015;128:1154-9.

Source of Support: This work was supported by a grant from Novartis China (No. CRFB002ACN02). **Conflict of Interest:** None declared.