Intravitreal Conbercept for choroidal neovascularisation secondary to pathological myopia in real-life setting in China

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Abstract

Background: To evaluate the 12-month efficacy and safety of intravitreal conbercept for myopic choroidal neovascularization (CNV).

Methods: A retrospective, observational study. Thirty-four eyes of 34 pathologic myopic patients with CNV were treated with intravitreal conbercept (IVC) 0.5 mg with a follow up of 12 months. After the first injection, administration of conbercept followed a pro re nata (PRN) regimen. Outcomes included best corrected visual acuity (BCVA), central retinal thickness (CRT), CNV size, the total number of treatments, and adverse events.

Results: The mean patient age was 55.88 ± 16.17 years, and mean eye spherical equivalent was − 8.72 ± 3.75 D. The mean number of IVC over 12 months was 2.12 ± 0.69. Overall, best-corrected visual acuity [BCVA] improved from 0.86 ± 0.33 logMAR at baseline to 0.44 ± 0.32 logMAR at month 12 (P < 0.001), mean improvement of vision was 4.12 ± 2.69 Snellen lines. Mean central retinal thickness reduced from 285.9 ± 104.6 μm at baseline to 192.1 ± 97.5 μm at month 12 (P < 0.001). Mean CNV size decreased from 0.52 ± 0.38 mm 2 at baseline to 0.31 ± 0.19 mm 2 at 12 months (P < 0.05). All the 34 eyes had reduced or stable size of CNV, thirty-two eyes (94.12%) showed absence of CNV leakage at the end of the study period. No severe complications were observed.

Conclusion: Intravitreal conbercept 0.5mg was safe and effective for treatment of myopic CNV over 12 months in real-life setting.

Introduction

Myopic choroidal neovascularization (CNV) is a common cause of vision impairment in young and middle-aged patients with pathologic myopia (PM) in China.[1–2] It has been reported that approximately 5% to 11% of patients with pathologic myopia will develop myopic CNV.[1–3] Previously, the standard treatment option for myopic CNV is
photodynamic therapy (PDT); however, the patients treated with PDT have limited long-term visual outcomes.[4] Recently, anti-vascular endothelial growth factor (anti-VEGF) drugs such as ranibizumab,[5-6] bevacizumab,[7] and aflibercept [8] have been used to treat myopic CNV with promising results. The study of PDT versus intravitreal bevacizumab (IVB) provided evidence for the superiority of intravitreal bevacizumab over PDT in treating myopic CNV.[9] The RADIANCE study demonstrated that intravitreal ranibizumab (IVR) provided significant visual improvement than PDT in patients with myopic CNV.[5] In the MYRROR trial, intravitreal aflibercept (IVA) was shown to be safe and effective in treating myopic CNV.[8] Anti-VEGF agents are now considered as a first-line therapy for subfoveal and juxtafoveal myopic CNV.[10-11]

Similar to aflibercept, conbercept is an engineered protein that contains the extracellular domain-2 of VEGF receptor (VEGFR) 1, and extracellular domains-3 and − 4 of VEGFR-2. The structural difference between conbercept and aflibercept is that conbercept also contains the fourth binding domain of VEGFR-2, which is essential for receptor dimerization and enhances the association rate of VEGF to the receptor.[12-13] Although few studies employing conbercept to treat myopic CNV have been reported, the effect of conbercept on patients with neovascular age-related macular degeneration (nAMD), polypoidal choroidal vasculopathy (PCV), macular edema after retinal vein occlusion (RVO) and diabetic macular edema (DME) were promising,[14-17] and was approved treat myopic CNV by the State Food and Drug Administration of China in May 2017. However, there is very few experience in intravitreal conbercept in patients with treatment myopic CNV in real-life setting. Therefore, this retrospective study aimed to evaluate 12-month outcomes of Chinese patients with myopic CNV treated with conbercept in a real-life setting.

Methods
Patients

The study was approved by the medical ethics committees of Chongqing General Hospital, and performed in compliance with the 1964 Declaration of Helsinki. We retrospectively reviewed the medical and clinical histories of 34 eyes of 34 consecutive patients with myopic CNV that were treated with intravitreal conbercept (IVC) with a follow-up of 12 months between August 2017 and March 2019.

At baseline and all subsequent visits, every patient underwent a complete ophthalmic examination, which included best corrected visual acuity (BCVA), tonometry, biomicroscopy, dilated fundus examination, and OCT (Cirrus; Zeiss, Germany). Fluorescein angiography was performed before the IVC, and also at 1, 2, 3, and 12 months after the IVC. Furthermore, Fluorescein angiography was conducted so as to confirm the presence of fluorescein leakage in the macular area. The CNV size was measured in the early-phase FA images.

Patients were included in the study if they were aged ≥ 18 years and had high myopia (spherical equivalent ≤ − 6.0 diopters or ocular axial length ≥ 26.5 mm). In addition, all patients must have had active subfoveal myopic CNV (as documented by spectral-domain optical coherence tomography [SD-OCT] and fluorescein angiography [FA]) and BCVA 20/800 or better at baseline. Patients were excluded if they had any one of the following: (1) history of (a) stroke; (2) CNV was secondary to causes other than pathologic myopia; (3) presence of any other ophthalmic diseases; (4) history of treatment with anti-VEGF drugs; (5) prior laser therapy or other intraocular surgery in the study eye; (6) intraocular pressure (IOP) ≥ 25 mmHg.

Intervention or observation procedure

Eligible patients were received 1 intravitreal injection of conbercept 0.5 mg at baseline,
conbercept was injected as needed following a pro-re-nata (PRN) schedule. Patients were examined each month for the first 3 months after the injection, and then every three months during the remainder of the follow-up. Re-treatment was not performed unless any of the following was present in the study eye: reduction in BCVA by 1 Snellen line; a more than 100 µm increase in central retinal thickness (CRT) on OCT; new, recurrent, or persistent subretinal or intraretinal fluid; CNV leakage on FA; and new macular hemorrhage.

Main outcomes measure

The primary objective was changed in BCVA from baseline to month 12 in patients with myopic CNV receiving IVC 0.5 mg. The secondary objectives included the following: change in CRT on OCT from baseline to month 12; change in CNV lesion size on FA from baseline to month 12; the number of conbercept injections administered during the 12-month study period; and ocular and systemic adverse events resulting from the injections at every study visit.

Statistical analysis

BCVA was assessed using the Snellen chart at 6 meters distance and was converted to logarithm of the minimum angle of resolution (LogMAR) for analysis. Data were presented as mean values ± standard error (SD). Statistical significance of the difference from baseline to 12 months in BCVA, CNV size and CRT was determined by Wilcoxon signed-rank test, Fisher’s exact test and paired t-test. Calculations were made with the SPSS Version 17.0 (SPSS, Chicago, IL, USA). A p value less than 0.05 was regarded as statistically significant.

Results

Baseline characteristics
Thirty-four eyes of 34 patients with active subfoveal myopic CNV were included and treated with at least 1 intravitreal conbercept in this study. A 12-month follow-up was completed in all patients. The baseline and clinical characteristics of these patients are shown in Table 1. There were 22 women (64.7%), and the mean age of the 34 patients was 55.88 ± 16.17 years with a range of 19 to 78 years. The average spherical equivalent was –8.72 ± 3.75 D with a range of –6.50 to –18.00 D; the average axial length was 27.35 ± 1.23 mm with a range of 26.50–32.52 mm. The CNV was seen for 18 right eyes (52.9%) and 16 left eyes (47.1%). All patients of CNV were presented with a predominantly classic in the macular area. The mean BCVA in LogMAR was 0.70 ± 0.56, the mean CRT at baseline was 285.9 ± 104.6 µm, and the mean size of the CNV before IVC was 0.52 ± 0.38 mm².

Table 1
Baseline Patient Demographics and Clinical Characteristics

| Characteristic                      | Patients, N = 34 (eyes, N = 34) |
|-------------------------------------|----------------------------------|
| Mean age (SD), yrs                  | 55.88 (16.17)                    |
| Sex, n (%)                          |                                  |
| Male                                | 22 (64.71)                       |
| Female                              | 12 (35.29)                       |
| Eye side, n (%)                     |                                  |
| Right                               | 18 (52.94)                       |
| Left                                | 16 (47.06)                       |
| Mean BCVA (SD), logMAR              | 0.70 (0.56)                      |
| Mean CRT (SD), µm                   | 285.9 (104.6)                    |
| Mean CNV size (SD), mm²             | 0.52 (0.38)                      |
| Mean IOP (SD), mmHg                 | 15.26 (3.21)                     |
| Mean axial length (SD), mm          | 27.35 (1.23)                     |
| Mean refraction-sphere (SD), diopters| –8.72 (3.75)                   |
| CNV location, n (%)                 |                                  |
| Subfoveal                           | 30 (88.23)                       |
| Juxtafoveal                         | 4 (11.76)                        |

**Visual and anatomical outcomes**

For the all cases, the mean BCVA logMAR increased significantly from 0.86 ± 0.33 at baseline to 0.44 ± 0.32 at month 12 (P < 0.001) (Fig. 1). The greatest improvement in BCVA was seen during the first 2 months (P < 0.001), and the BCVA remained stable afterwards (Fig. 1). The mean improvement in visual acuity was 4.12 ± 2.69 Snellen lines with a range of 0 to 9 lines at Month 12, an improvement in BCVA of ≥ 3 lines was seen in nineteen eyes (55.9%), eighty eyes (23.5%) an improvement by ≥ 2 but < 3 lines, and
three eyes (8.8%) an improvement by ≥ 1 but < 2 lines. BCVA was unchanged in four eyes (11.8%). None of the treated eyes lost ≥ 1 line of vision.

The mean CRT reduced significantly from 285.9 ± 104.6 µm at baseline to 192.1 ± 97.5 µm at month 12 (P < 0.001) (Fig. 2). The greatest improvement in CRT was seen during the first 2 months (P < 0.001), and the CRT remained stable afterwards (Fig. 2). At month 12, subretinal or intraretinal fluid completely disappeared as assessed by OCT in 32 (94.1%) eyes.

Finally, in terms of the mean CNV size, patients with intravitreal conbercept showed a reduce from 0.52 ± 0.38 mm² at baseline to 0.31 ± 0.19 mm² at month 12 (P < 0.05). FA showed significant reduction of mean CNV size at month 2 (P < 0.05). An absence of CNV angiographic leakage was observed by FA in 32 eyes (94.1%), while slight leakage persisted in 2 eyes (5.8%) at Month 12. All the 34 eyes had reduced or stable size of CNV at the last visit.

**Number of Intravitreal Conbercept Injections**

Overall, the mean number of IVC was 2.12 ± 0.69 with a range of 1 to 4 in all of the 34 eyes. In detail, during a 12-month follow-up, 4 eyes of the 34 patients (11.8%) received one injection, 24 eyes (67.7%) received two injections, 4 eyes (11.8%) received three injections, and 2 eyes (5.9%) received four injections. In addition, twenty-eight eyes (82.4%) needed one to two additional injections in subsequent months after the first injection because of persistent leakage. Two eyes (5.9%) had recurrence at month 6 and month 9 respectively, and required two additional injections in subsequent months.

**Complications**

There were no deaths and no cases of cerebrovascular events, endophthalmitis, uveitis, or retinal detachment reported in this study. None of the treated patients demonstrated an
IOP elevation during any study visit. The most frequent ocular adverse events in the study were conjunctival hemorrhage (4/34, 11.8%), punctate keratitis (2/34, 5.9%), and eye pain (3/34, 8.8%).

Discussion

The current study assessed the efficacy and safety of intravitreal conbercept in a 1 + PRN regimen as the primary treatment for myopic CNV. Our results showed that intravitreal conbercept provided the significant BCVA improvement with fewer injections over 12 months. Further, Treatment with conbercept also showed promising anatomical results. CNV size and CRT reduced significantly at the end of follow up compared with baseline. In addition, no severe complications were observed. Taken together, these outcomes demonstrated that conbercept was efficacy and safety in treating patients with myopic CNV.

In recent years, several studies have demonstrated the promising efficacy of anti-VEGF therapy for the treatment of myopic CNV and have concluded the use of these agents as first-line therapy for this condition. Ranibizumab was the first anti-VEGF drug approved for the treatment of myopic CNV, having been shown to be more effective than PDT. The efficacy of ranibizumab was confirmed by the RADIANCE study, which demonstrated that BCVA gains were significantly superior with intravitreal ranibizumab than PDT up to week 12, and ranibizumab treatment alone was effective in further improving and sustaining BCVA in pathologic myopic patients with CNV over 48 weeks.[5] In the REPAIR study, patients received a single injection of ranibizumab followed by a PRN strategy. There was a mean BCVA improvement of 13.8 letters after 48 weeks with a median of 3 injections.[6] Aflibercept has also been reported to be useful for the treatment of CNV secondary to PM. In the MYRROR study, which reported that a mean BCVA increase of 13.5 letters in aflibercept-treated patients compared with + 3.9 letters in sham-treated patients and
maintenance of gains in BCVA up to 48 weeks, Patients received a median of 2.6 injections within the first 12 weeks. Visual improvement was maintained for up to 48 weeks. Conbercept is a novel anti-VEGF reagent with several structural similarities to aflibercept, that it binds not only VEGF-A, but also VEGF-B, VEGF-C, and placental growth factor (PIGF). Conbercept and aflibercept differ structurally in that conbercept contains a fourth VEGFR-2 binding domain, one that perhaps enhances the association rate of VEGF and prolongs its half-life in the vitreous. The results of our retrospective study of 34 patients, are general agreement with those noted in the MYRROR trial, with a mean improvement in BCVA of 2.38 ± 2.61 Snellen lines at 12 months, achieved with a mean number of 2.12 ± 0.69 injections. In addition, the BCVA greatest increase was seen during the first 2 months, and the BCVA remained stable afterwards. Among these patients, the mean improvement was 4.12 lines, with 88% experienced visual improvement and 79% of treated eyes demonstrating an improvement of ≥ 2 Snellen lines. All the 34 eyes demonstrated improved or stable vision up to month 12. Treatment with conbercept also improved anatomical results. CRT reduced significantly at the end of follow up compared with baseline, and mean CNV size significantly decreased. All the 34 eyes had reduced or stable size of CNV, 32 eyes (94.12%) showed a complete closure of CNV on FA at the last visit. In addition, no serious local or systemic adverse events were noted.

In addition, in a prospective study by Korol AR et al, a mean 2.6 injections in 31 eyes with myopic CNV treated with aflibercept within a 12-month follow-up; of these, 87% experienced visual improvement, 61% eyes increased two lines or more. Conbercept seems to be as effective as aflibercept monotherapy in term of treating myopic CNV. Several reports have supported 3 + PRN regimen to treat myopic CNV. However, many other trials have demonstrated that 1 + PRN is also effective. The results of two different initial dosing schedules of intravitreal ranibizumab for the treatment of CNV secondary to
PM have been compared, demonstrating that similar visual improvement was attained in both injection strategies.[19] Moreover, 1 + PRN regimen received 1.37 fewer injections than 3 + PRN regimen over 12 months.[11] These results indicated that one single injection followed by PRN might be a reasonable choice for myopic CNV. Our results also demonstrated that a single initial injection of conbercept for myopic CNV required fewer injections, and provided significant BCVA improvement over 12 months. In detail, four eyes (11.8%) received one injection, twenty-eight eyes (82.4%) needed one to two additional injections after initial injection, and only 2 eyes (5.9%) showed recurrence at the end of 12 months. Most notable, the greatest improvement in BCVA was seen in the first 2 months in our study, with minimal subsequent re-injections. For the decreased number of Conbercept injections that were needed, this can be explained by the features of conbercept compared with the other anti-VEGF drugs and by the reduced aggressiveness of CNV secondary to PM compared with nAMD. Indeed, the AURORA trial demonstrated that for the treatment of CNV due to nAMD, conbercept sustained the visual improvement achieved with fewer injections within a 12-month follow-up.[16] Furthermore, myopic CNV is different from other indications for anti-VEGF therapeutics, such as nAMD or DME, proactive treatment is required to achieve sustainable and optimal efficacy.

Regarding the prognostic factors, several studies pointed out the total number of injections associated significantly with age, myopic refraction, CNV size, and CNV location at baseline.[20] The total number of injections may be another indicator of myopic CNV activity as well as its recurrence. In the current study, four eyes (11.8%) showed complete resolution of CNV activity after just one IVC. This resolution rate is markedly lower than the resolution rate of 54.7% by Bruè C et al[21], who focused on both subfoveal and extrafoveal myopic CNV. In addition, 2 eyes (5.9%) showed recurrence, those patients who
required relatively more frequent IVC had larger CNVs. Thus, our study indicated that subfoveal CNV lesion and larger CNV lesion tended to have more numbers of injections.

Conclusions

This retrospective study showed that 1 + PRN intravitreal conbercept is a safe and effective treatment for myopic CNV, and that visual improvement can be maintained over 12 months. However, our study was retrospective, had a small sample size, and conducted in a single ophthalmologic institution. In the future, further multi-center, randomized, long-term, and controlled studies are still needed to validate these findings.

Abbreviations

BCVA
Best corrected visual acuity; CNV: Choroidal neovascularization; CRT: Central retinal thickness; FA: Fluorescein angiography; LogMAR: Logarithm of the minimum angle of resolution; OCT: Optical coherence tomography; PRN: pro-re-nata; PM: Pathological myopia; VEGF: Vascular endothelial growth factor; IVC: Intravitreal conbercept.

Declarations

Acknowledgments

We thank all the patients who participated in this study.

Authors’ contributors

Design and conduct of the study (YQ and XN); data collection and management (XN, YW, and YQ); analysis and interpretation of data (YQ and XN); writing the article (XN); critical revision of the article (YQ and HY). All authors have read and approved the final manuscript.

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Technology Innovation Foundation (2016ZDXM01).

**Competing interests**

None

**Ethics approval and consent to participate**

Approval was obtained by the medical ethics board of Chongqing General Hospital. Written consents were obtained from all the recruited patients.

**Availability of data and materials**

The datasets used and/or analyzed during the current study available from the corresponding author on reasonable request.

**Consent for publication**

Not applicable.

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Tables

Table 1 Baseline Patient Demographics and Clinical Characteristics
| Characteristic                        | Patients, N = 34 (eyes, N = 34) |
|--------------------------------------|----------------------------------|
| Mean age (SD), yrs                   | 55.88 (16.17)                    |
| Sex, n (%)                           |                                  |
| Male                                 | 22 (64.71)                       |
| Female                               | 12 (35.29)                       |
| Eye side, n (%)                      |                                  |
| Right                                | 18 (52.94)                       |
| Left                                 | 16 (47.06)                       |
| Mean BCVA (SD), logMAR               | 0.70 (0.56)                      |
| Mean CRT (SD), μm                    | 285.9 (104.6)                    |
| Mean CNV size (SD), mm²              | 0.52 (0.38)                      |
| Mean IOP (SD), mmHg                  | 15.26 (3.21)                     |
| Mean axial length (SD), mm           | 27.35 (1.23)                     |
| Mean refraction-sphere (SD), diopters| – 8.72 (3.75)                    |
| CNV location, n (%)                  |                                  |
| Subfoveal                            | 30 (88.23)                       |
| Juxtafoveal                          | 4 (11.76)                        |

**Figures**
Figure 1

Mean change in best-corrected visual acuity (BCVA) over 12 months. The greatest improvement in BCVA was seen within the first 2 months (P < 0.001), and the BCVA remained stable afterwards. Error bar represents standard deviation.
Mean change in central retinal thickness (CRT) over 12 months. The greatest improvement in CRT was seen within the first 2 months ($P < 0.001$), and the CRT remained stable afterwards. Error bar represents standard deviation.