Ranibizumab or Aibercept for Neovascular Age-Related Macular Degeneration, Twelve-Month Outcomes of Therapeutic Program in Non-Tertiary Institution: A Comparative Study.

Tomasz Skrzypczak (✉ tomasz.skrzypczak@student.umed.wroc.pl)
Wroclaw Medical University: Uniwersytet Medyczny im Piastow Slaskich we Wroclawiu
https://orcid.org/0000-0003-4030-9101

Aleksandra Jany
Wroclaw Medical University: Uniwersytet Medyczny im Piastow Slaskich we Wroclawiu

Ewa Bugajska-Abramek
Wojewodzki Szpital Specjalistyczny we Wroclawiu

Joanna Bogusławska
Wojewodzki Szpital Specjalistyczny we Wroclawiu

Agnieszka Kowal-Lange
Wojewodzki Szpital Specjalistyczny we Wroclawiu

Research Article

Keywords: Age-related macular degeneration, Ranibizumab, Aibercept, AMD

DOI: https://doi.org/10.21203/rs.3.rs-425927/v1

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Abstract

**Purpose:** This single center study aimed to compare the 12-month treatment outcomes of ranibizumab with that of afibercept in routine clinical practice.

**Methods:** Cohort of patients diagnosed with treatment-naive neovascular AMD, treated using either ranibizumab (n = 33 eyes) or afibercept (n = 44 eyes) monotherapy over a 12-month follow-up period was analyzed. Anonymous data were extracted from the electronic database dedicated to the drug program.

**Results:** In the ranibizumab group, there were not statistically significant changes in BCVA (ETRDS letters) and CRT (µm), between baseline (67.9 ± 8.6 & 384.9 ± 97.9) and at 12 months (67.9 ± 12.1 & 398.9 ± 127.1; P = 0.372 & P = 0.884, respectively). In the afibercept, there was an improvement in BCVA and reduction in CRT between baseline (64.2 ± 8.1 & 414.3 ± 97.8) and at 12 months (70.7 ± 7.4 & 342.3 ± 71.6; P<.001 & P<.001, respectively). There was no difference in BCVA between the two groups at either diagnosis (P= 0.101) or 12 months (P= 0.917). Mean number of injections in the ranibizumab group was significantly lower (4.9 ± 1.5) than in the afibercept group (6.7 ± 1; P<.001).

**Conclusions:** One initial injection of ranibizumab and then PRN regimen resulted in stabilization of disease progression. Drug selection and treatment scheme could influence twelve-months outcomes. In the afibercept group, three initial monthly injections and then every two months provided both significant BCVA improvement and CRT reduction at 12 months of treatment.

Introduction

Age-related macular degeneration (AMD) is a chronic disease that affects around 50–70 million people worldwide and is the leading cause of blindness in developed countries, including Poland. The treatment of choice for wet AMD is intravitreal injection of vascular endothelial growth factors inhibitors (VEGF). Although anti-VEGF therapy is focused at treating symptoms, it has revolutionized the treatment of exudative AMD.

Since November 2015, treatment of patients with wet AMD in Poland has been financed by the National Health Found (NHF). Two drugs, afibercept or ranibizumab are administrated as part of the Polish National Treatment Program. The authors aimed to compare effectiveness of ranibizumab and afibercept, in non-tertiary institution.

Material And Methods

Study design

This was a non-randomized, retrospective, observational single center study of treatment-naive eyes for wet-AMD. Anonymous data were collected from the drug program dedicated electronic database. Records from December 2015 to December 2020 were analyzed.

Data included the assessment of the following: the best corrected visual acuity (BCVA) on a decimal scale made on the basis of a Snellen chart, macular morphology with automatic measurement of the central retina thickness (CRT) from the central subfield of the optical coherence tomography (OCT); percentage share of active area in degenerative lesion, size of degenerative lesion (DA). Type of neovascularization was determined with fluorescein angiography (FA). All OCT scans were performed on certified spectral domain OCT (Spectralis OCT, Heidelberg Engineering, Germany). In addition, possible prior treatment with VEGF inhibitors, disease activity defined as the presence of sub- or intra-retinal fluid in OCT or a new hemorrhage were reported.

Demographic factors extracted from the database were age (years), gender, eye (right/left), date of diagnosis, dates and number of injections with VEGF inhibitors.

Treatment program

The following inclusion criteria were applied in the treatment program: 1) presence of active (primary degeneration, not secondary) occult (type 1), classic (type 2) or mixed (other than pure classic or occult, including retinal angiomatous proliferation – type 3) Subretinal choroidal neovascularization (CNV) occupying more than 50% of the lesion; 2) age ≥ 45 years 3) total size of degenerative lesion less than 12 optic disc area (DA); 3) BCVA in the treated eye of 0.1–0.8 (from 2015 to 2017); 0.2–0.8 (from 2017 to present), determined on a decimal scale according to the Snellen chart; 4) absence of dominant geographic atrophy or hemorrhage in the whole...
lesion (more than 50% of the lesion); 6) informed consent of the patient to undergo intravitreal injections. Patients with scarring or atrophy of the fovea were not eligible for the treatment.

BCVA deterioration to ≤ 0.05 according to Snellen’s chart lasting longer than 2 months excluded patient from the program. In addition, physician could remove the patient from the program according to the exclusion criteria contained in summary of product characteristics.

Aibercept or ranibizumab were chosen by the physician at the time of the first injection. Ranibizumab was mainly administrated in cases which were expected to improve rapidly, allowing for a prompt withdrawal from the therapeutic program. All eyes were treated with fixed regimen, according to the “Treatment of neovascular form of age-related macular degeneration” National Health Found program guidelines.\(^6\)

Three monthly intravitreal injections of aibercept (2.0 mg/0.05mL) were administrated and then drug was injected every 2 months. After the first 12 months of aibercept treatment, a pro re nata (PRN) regimen was in force. In patients treated with ranibizumab, after administering the initial dose (0.5 mg/0.05mL) the PRN scheme was applied. Patients received injections monthly until the disease was no active and functional stability was achieved. Then, patients were followed-up for 4–8 weeks. Ranibizumab was given again, when active neovascularization recurred, and functional parameters worsened. Physician could switch drug if the patient met both of the following criteria: 1) BCVA after 7 injections of ranibizumab or aibercept (since inclusion to the program) was worse than BCVA at baseline; 2) patient still met the inclusion criteria for therapeutic program. Switch from ranibizumab to aibercept and vice versa was permitted. However, patients which drug was switched during the therapy were excluded from the analysis.

Clinical examinations, OCT and measurement of BCVA were performed at each follow-up visit and recorded in the electronic database. Patients with follow-up period cript > 12 months were excluded from the analysis. Only, patients with treatment-naïve wet AMD eyes and complete medical records were included in the study.

Changes after 12-month treatment.

The baseline BCVA and CRT were compared with those at 12 months within each treatment group.

Comparisons between the ranibizumab group and aibercept group.

Eyes were divided into two groups: the ranibizumab (n = 33) and aibercept groups (n = 44). These were compared in terms of baseline characteristics (BCVA, CRT, percentage share of active area in degenerative lesion, size of degenerative lesion, neovascularization type, age and sex). In addition, the BCVA, CRT and number of injections after 12 months of treatment were compared between groups.

To investigate difference between good visual outcome and poor visual outcome, eyes were divided into two groups on the basis of BCVA at 12 months. These with BCVA ≥ 20/50 were assigned to the “good visual outcome” group. Patients with BCVA cript > 20/50 were included in the “poor visual outcome” group. Within each treatment group, the visual outcomes were compared in terms of baseline characteristics (mentioned above) and number of injections.

The patients were divided into two groups, according to the number of injections received within 12-month treatment period. Mean number of injections were calculated for ranibizumab and aibercept groups. Patients, whose number of injections was ≥ than mean in their drug group were compared against these, whose number of injections was cript > than mean in their drug group. The BCVA and CRT at baseline and at 12 months were compared between these groups.

For the purpose of the study, visual acuity was calculated from the Snellen decimal scale to the number of ETRDS letters.\(^7\) The CRT values were reported in µm.

Statistics

Statistical analyses were performed with open-source software JASP, version 0.14.1, https://jasp-stats.org. Data were collected with use of Microsoft Excel software, version 16.46, (Microsoft Corporation, Redmond, WA, USA). The normality of data was examined with Shapiro - Wilk test. Differences between two time points were analyzed using the Wilcoxon signed - rank test. To analyze differences involving parametric values between two groups, either the independent t test or the Mann - Whitney U test were utilized. These that concerned non-parametric values were analyzed using the chi-square test. P values < .05 were considered significant. Data were presented as mean ± standard deviation (SD), where applicable.
Results

During the analyzed period, 67 patients (77 eyes) met the eligibility criteria. Both eyes of 10 patients (14.9%) were enrolled in the study. The mean age was 80.3 ± 7.4 years. The ranibizumab group consisted of 33 eyes and the aflibercept included 44 eyes. Table. 1.

Changes in BCVA and CRT

In the ranibizumab group, the BCVA values at diagnosis, 3 months and 12 months were 67.9 ± 8.6, 67.1 ± 17.2, 67.9 ± 12.2, respectively (Fig. 1). Neither BCVA at 3 months nor BCVA at 12 months changed significantly from baseline (P = 0.284 & P = 0.372, respectively). There was not significant change in BCVA between 3 and 12 months (P = 0.687). The CRT values at diagnosis, 3 months and 12 months were 384.9 ± 97.9, 381.4 ± 119, 400 ± 126.8, respectively (Fig. 2). There were no statistically significant differences in CRT values between baseline, 3 and 12 months (P = 0.334 & P = 0.884, respectively). In addition, the difference between CRT values at 3 and 12 months was not statistically significant.

In the aflibercept group, the BCVA values at diagnosis, 3 months, and 12 months were 64.2 ± 8.1, 69.4 ± 8, 70.7 ± 7.4, respectively (Fig. 1). The BCVA values at 3 and 12 months significantly improved from baseline (P < .001 & P < .001). The difference between BCVA values at 3 and 12 months was not significant (P = 0.332). The CRT values at diagnosis, 3 months and 12 months were 414.3 ± 97.8, 364.02 ± 104, 342.3 ± 71.6, respectively (Fig. 2). CRT values at 3 and 12 months were significantly lower than at baseline (P = 0.005 & P < .001, respectively). CRT significantly decreased between 3 and 12 months, (P = 0.036).

Table 2 summarized the results of comparison between the ranibizumab and aflibercept groups. From factors listed above, only number of injections differed significantly. In the ranibizumab group, patients received 4.9 ± 1.5 injections. In the aflibercept this was significantly higher 6.7 ± 1, (P < .001). In the ranibizumab group, 11 (33%) eyes received < 5 injections. There were not statistically significant changes between baseline BCVA, CRT and 12months BCVA, CRT in eyes, which received < 5 injections (P = 0.108 & P = 0.929 & P = 0.077, respectively). 22 eyes (66%) received ≥ 5 injections in the ranibizumab group. There were not statistically significant changes between baseline BCVA, CRT and 12months BCVA, CRT in these eyes (P = 0.842 & P = 0.702 & P = 0.136, respectively). In the aflibercept, 9 (20%) eyes, received < 7 injections. There were not significant changes between baseline BCVA&CRT and 12months BCVA&CRT for these eyes (P = 0.213 & P = 0.133 & P = 0.548, respectively). 35 eyes (80%) received ≥ 7 injections of the aflibercept. In this group, baseline BCVA (63.4 ± 9.1) significantly improved after 12 months of treatment (68.9 ± 10.1; P < .001). There was significant decrease in CRT (P < .001), from 422.8 ± 102.5 at baseline to 341.2 ± 69.9 at 12 months.
Table 1
Baseline patient characteristics (n = 67), 77 eyes.

| Characteristics                                      |       |
|-----------------------------------------------------|-------|
| Age, years                                          | 80.3 ± 7.4 |
| Sex, no. (%)                                        |       |
| Men                                                 | 27 (40.3%) |
| Women                                               | 40 (59.9%) |
| Type of neovascularization, no. (%)                 |       |
| Classic (type 2)                                    | 24 (31.2%) |
| Occult (type 1)                                     | 24 (31.2%) |
| Mixed                                               | 29 (37.6%) |
| Size of lesion (DA)                                 | 2.66 ± 0.02 |
| Surface (%)                                         | 60% ± 7% |
| Central retinal thickness (CRT, µm)                 | 401.7 ± 98.3 |
| Baseline BCVA (ETRDS), at diagnosis                 | 65.9 ± 9.2 |

Data presented as mean ± standard deviation where applicable.
Abbreviations: BCVA best-corrected visual acuity, ETRDS Early Treatment Diabetic Retinopathy Study
Table 2
Comparisons of characteristics between patients treated using aflibercept (aibercept group) and those treated using ranibizumab (ranibizumab group).

|                          | Aflibercept (n = 44) | Ranibizumab (n = 33) | P value |
|--------------------------|----------------------|----------------------|---------|
| **Baseline**             |                      |                      |         |
| Age, years               | 81.3 ± 7.3           | 78.8 ± 7.4           | 0.173*  |
| Sex, no. (%)             |                      |                      | 0.717†  |
| Men                      | 15 (38.5%)           | 12 (42.8%)           |         |
| Women                    | 24 (61.5%)           | 16 (57.2%)           |         |
| Type of neovascularization, no (%) |          |                      | 0.474†  |
| Classic                  | 15 (34%)             | 9 (27.3%)            |         |
| Occult                   | 15 (34%)             | 9 (27.3%)            |         |
| Mixed                    | 14 (32%)             | 15 (45.4%)           |         |
| Size of lesion, DA       | 2.6 ± 1.3            | 2.7 ± 1.4            | 0.849*  |
| Surface (%)              | 60% ± 7%             | 60% ± 7%             | 0.843*  |
| Central Retinal Thickness, µm | 414.3 ± 97.8   | 384.9 ± 97.9         | 0.158‡  |
| BCVA (ETRDS)             | 64.2 ± 9.3           | 67.9 ± 8.6           | 0.101‡  |
| After treatment at 12 months |                    |                      |         |
| Central Retinal Thickness, µm | 345.4 ± 73.7   | 398.9 ± 127.2         | 0.073‡  |
| BCVA (ETRDS)             | 69.1 ± 9.4           | 68.1 ± 12.2          | 0.917‡  |
| Number of injections     | 6.7 ± 1              | 4.91 ± 1.5           | < .001‡ |

Data presented as mean ± standard deviation where applicable.

Abbreviations: BCVA best-corrected visual acuity, ETRDS Early Treatment Diabetic Retinopathy Study

* Statistical analysis performed using the independent samples t test
† Statistical analysis performed using the chi-square test
‡ Statistical analysis performed using the Mann-Whitney U test

The results of comparison of baseline characteristics between the good visual outcome and poor visual outcome groups were presented in Table 3 (aflibercept group) and Table 4 (ranibizumab group). In the ranibizumab group, the good visual outcome group contained 21 (75%) eyes and the poor visual outcome group 7 (25%). The BCVA at diagnosis was significantly better (P = 0.007) in the good visual outcome group (70.2 ± 7.6) than in the poor visual outcome group (60.6 ± 7.9). In addition, the prevalence of type 1 neovascularization was significantly greater in the good visual outcome group (60%), than in the poor visual outcome group (0%; P < .001). In the aflibercept group, the good visual outcome group contained 30 (77%) eyes and the poor visual outcome group contained 9 (23%) eyes. The BCVA at diagnosis was significantly better (P = 0.021) in the good visual outcome group (66.3 ± 8.1) than in the poor visual outcome group (56.7 ± 10.3).
Table 3
Comparisons of baseline characteristics on the basis of the best-corrected visual acuity at 12 months (≥ 20/50 or < 20/50) in patients treated with aflibercept.

| Characteristics             | BCVA ≥ 20/50 (n = 30) | BCVA < 20/50 (n = 9) | P value |
|-----------------------------|------------------------|----------------------|---------|
| Age, years                  | 82.1 ± 7.2             | 78.9 ± 7.7           | 0.341†  |
| Sex, no. (%)                |                        |                      | 0.25†   |
| Male                        | 13 (43.3%)             | 2 (22.2%)            |         |
| Female                      | 17 (56.7%)             | 7 (77.8%)            |         |
| Type of neovascularization, no. (%) |              |
| Classic                     | 11 (31.4%)             | 4 (44.4%)            | 0.26‡   |
| Occult                      | 14 (40%)               | 1 (11.2%)            |         |
| Mixed                       | 10 (28.6%)             | 4 (44.4%)            |         |
| Size of lesion, DA          | 2.5 ± 1.2              | 3 ± 1.7              | 0.554‡  |
| Surface (%)                 | 60% ± 7%               | 61% ± 5%             | 0.470‡  |
| Central Retinal Thickness, µm | 423.6 ± 100.8          | 374.3 ± 77.7         | 0.20‡   |
| BCVA (ETRDS), at diagnosis  | 66.3 ± 8.1             | 56.7 ± 10.4          | 0.021‡  |
| Number of injections        | 6.7 ± 1                | 6.9 ± 0.8            | 0.609‡  |

Data presented as mean ± standard deviation where applicable.

Abbreviations: BCVA best-corrected visual acuity, ETRDS Early Treatment Diabetic Retinopathy Study
† Statistical analysis performed using the chi-square test
‡ Statistical analysis performed using the Mann-Whitney U test
Table 4
Comparisons of baseline characteristics on the basis of the best-corrected visual acuity at 12 months (≥ 20/50 or < 20/50) in patients treated with ranibizumab.

| Characteristics                          | BCVA ≥ 20/50 (n = 21) | BCVA < 20/50 (n = 7) | P value |
|------------------------------------------|------------------------|---------------------|---------|
| Age, years                               | 78.2 ± 7.4             | 80.7 ± 7.9          | 0.447†  |
| Sex, no. (%)                             |                        |                     |         |
| Male                                     | 11 (52.4%)             | 1 (14.3%)           | 0.077†  |
| Female                                   | 10 (47.6%)             | 6 (85.7%)           |         |
| Type of neovascularization, no. (%)      |                        |                     | <.001†  |
| Classic                                  | 5 (20%)                | 4 (50%)             |         |
| Occult                                   | 15 (60%)               | 0 (0%)              |         |
| Mixed                                    | 5 (20%)                | 4 (50%)             |         |
| Size of lesion, DA                       | 2.4 ± 1                | 3.6 ± 1.9           | 0.129‡  |
| Surface (%)                              | 60% ± 7%               | 60% ± 8%            | 0.989‡  |
| Central Retinal Thickness, µm            | 374.2 ± 76.5           | 418.6 ± 148.6       | 0.721‡  |
| BCVA (ETRDS), at diagnosis               | 70.2 ± 7.6             | 60.6 ± 7.9          | 0.007‡  |
| Number of injections                     | 4.9 ± 1.6              | 5.0 ± 1.2           | 1.000‡  |

Data presented as mean ± standard deviation where applicable.

Abbreviations: BCVA best-corrected visual acuity, ETRDS Early Treatment Diabetic Retinopathy Study

† Statistical analysis performed using the chi-square test
‡ Statistical analysis performed using the Mann-Whitney U test

Discussion

In the present study, one initial injection of ranibizumab and then PRN regimen resulted in stabilization of neovascular AMD progression. The twelve month outcomes of treatment with ranibizumab were different than revealed in other studies.\(^8\)\(^{-}\)\(^10\) Retrospective, observational studies\(^8\)\(^{-}\)\(^10\) reported both significant improvement in BCVA and reduction in CRT at 12 months. Eyes treated with ≥ 5 number of injections had similar results as eyes, that received < 5 injections. Observed outcomes could be associated with administration of ranibizumab to eyes with better prognosis at baseline. This might result in lower BCVA improvement and CRT reduction at 12 months. In addition, these eyes might receive less injections. According to recommendations of the drug programme,\(^6\) ranibizumab was administered in PRN scheme. None of the analyzed patients received initial 3 monthly injections. This could also explain different outcomes than in cited studies.

Aflibercept was found to be effective in treating patients with the neovascular AMD. There was statistically significant visual acuity improvement and CRT reduction. At 12 months patients gained 4.9 ± 8.5 ETRDS letters and CRT was reduced by 72 ± 30 µm, form the baseline. Similar results were revealed in other retrospective, observational studies with 12-months follow up.\(^11\)\(^{-}\)\(^15\) Less than 7 injections resulted in non-significant change in BCVA and CRT. This coincides with other authors findings. Treatment-naïve wet AMD eyes receiving fewer than 7 intravitreal aflibercept injections in the first year of treatment had worse visual outcomes.\(^16\)\(^{-}\)\(^18\)

In the present study, good baseline BCVA was associated with visual acuity of 20/50 or better at 12 months in both the ranibizumab and aflibercept groups. Previous studies showed that type 1 neovascularization was associated with a better long term visual outcome than other subtypes of neovascularization.\(^15\)\(^,\)\(^19\) In ranibizumab group, the proportion of cases involving type 1 neovascularization was greater...
in the good visual outcome than in the poor visual outcome group. This trend was not revealed in the aflibercept group. The difference in the ranibizumab group, could be potentially due to the small sample size. However, this was statistically significant.

The main limitation of this study was its retrospective, single center nature. There were a relatively small number of patients and short follow-up period. The authors aimed to evaluate effectiveness of anti-VEGF therapy in the setting of regional hospital.

To conclude, 3 monthly intravitreal injections of aflibercept (2.0 mg/0.05mL) and then every 2 months was an effective treatment regimen of naïve wet AMD eyes. This resulted in significant BCVA improvement and CRT reduction at 12 months of therapy. One initial monthly injection of ranibizumab (0.5 mg/0.05mL) and then PRN regimen resulted in stabilization of the disease progression, for 12 months follow-up period in naïve wet AMD eyes.

**Declarations**

**Acknowledgements**

The authors did not receive support from any organization for the submitted work.

**Author contributions**

AKL, JB and EBA contributed to the study conception, design and execution. EBA, TS and AJ were responsible for data collection. Material preparation was performed by AJ and TS. TS analyzed the data and wrote the first draft of the manuscript. All authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

**Data availability**

The anonymized patients’ data used to support the findings of this study are available from the corresponding author upon request.

**Funding**

The authors received no financial support for the research, authorship and publication of this article.

**Conflict of interest**

The authors declare that there is no conflict of interest regarding the publication of this paper.

**Code availability**

Not applicable

**Ethics approval**

This study was approved by the hospital bioethical committee and conducted in accordance with the tenets of the Declaration of Helsinki.

**Consent to participate**

Not applicable, due to retrospective, observational, anonymous nature of this study.

**Consent for publication**

Not applicable, due to retrospective, observational, anonymous nature of this study.

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Figures
Figure 1

Changes in BCVA in patients treated with ranibizumab or aflibercept.

Figure 2

Changes in CRT (µm) in patients treated with ranibizumab or aflibercept.