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Research Article

Anti-VEGF Treatment Outcome of Neovascular Age-Related Macular Degeneration: A Low-Income Country Experience

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Abstract

Purpose: To evaluate the real-world outcomes of anti-VEGF treatment for neovascular age-related macular degeneration (NvAMD) in a low-income country setting.

Methods: A retrospective cohort study was conducted at Nisir Specialized Eye Clinic in Addis Ababa, Ethiopia, involving 159 eyes of 142 patients who received at least three intravitreal anti-VEGF injections from September 2021 to August 2023. The primary outcome was the change in central macular thickness (CMT); secondary outcomes included improvements in visual acuity (VA), the number of injections, and complications.

Results: A total of 159 eyes of 142 study participants were included in this study; the mean age of participants was 68.7 years; 52.8% were female. Bevacizumab was used in 79.2% of cases, with a mean of 3.42 injections per eye. Baseline mean CMT was 358.50 µm, reducing to 256.93 µm at 3 months and 258.55 µm at 12 months (mean reduction of 104.22 µm and 118.42 µm, respectively). Visual acuity improved from 20/400 - 20/630 at baseline to 20/50 - 20/200 in 46.5% of eyes by 3 and 12 months. Only baseline CMT was significantly associated with 3-month VA ($p < 0.001$). Most patients (83.6%) discontinued treatment after three injections, primarily due to financial constraints. Complications were observed in 4.4% of eyes, with endophthalmitis being the most common.

Conclusion: Anti-VEGF treatment in this low-income setting showed modest improvements in CMT and VA, but outcomes were limited by under-treatment, largely due to cost. This underscores the need for resource-adjusted treatment protocols and enhanced patient support to improve long-term outcomes.

Keywords: *anti-VEGF; Nv AMD*

Abbreviations

AMD: Age-Related Macular Degeneration; CMT: Central Macular Thickness; CNV: Choroidal Neovascularization; ETDRS: Early Treatment Diabetic Retinopathy Study; FDA: Food and Drug Administration; GA: Geographic Atrophy; NvAMD: Neovascular Age-Related Macular Degeneration; PED: Pigment Epithelial Detachment; PRN: Pro Re Nata; RPE: Retinal Pigment Epithelium; VA: Visual Acuity; VEGF: Vascular Endothelial Growth Factor

Introduction

Background

Macular degeneration is the leading cause of severe visual loss in people above the age of 55. As this disease occurs with age, it is known as age-related macular degeneration (AMD) [1]. The cause of the visual loss is mainly either due to neovascular" wet" AMD or geographic atrophy (GA) [2]. It has been shown that worldwide, 8.7% of the population has AMD, with numbers expected to increase from 196 million in 2020 to 288 million in 2040. It is projected that by 2040, there will be 39 million people in Africa with AMD [3]. Population-based studies in Africa have shown the prevalence of early AMD to be 11.2% and that of neovascular AMD (NvAMD) to be 1.2% [4].

Various classification schemes exist, but the AREDS publication describes AMD in terms of early, intermediate, and late stages. The late stage includes NvAMD and GA. The pathophysiology of AMD is complex and not fully understood. It involves mechanisms such as retinal pigment epithelium (RPE) cell aging, oxidative stress, lipid metabolism, and inflammation that contribute to disease development.

Until the early 2000s, there was no effective treatment for NvAMD. The advent of anti-VEGF (Vascular Endothelial Growth Factors) has revolutionized care [6]. Pegaptanib was the first FDA-approved anti-VEGF used for NvAMD [7]. Since then, there have been the addition of ranibizumab, aflibercept, brolucizumab, together with their biosimilars and the non-FDA-approved anti-VEGF-bevacizumab. Several studies have shown numerous predictors of outcome. Namely, age, baseline visual acuity (VA), and choroidal neovascularization size will determine treatment outcomes; those with younger age at presentation, smaller lesion size, and better baseline VA will have better outcomes [8]. Monthly injections, treatment, extended, and as needed are the major treatment strategies employed with anti-VEGFs. In low-income countries, strict protocols can't be followed mainly due to financial constraints.

AMD is becoming quite prevalent throughout the world, with numbers in mainly white populations showing prevalence as high as 13% [9]. There is currently no cure for the disease, but treatment with Anti-VEGF is the mainstay of treatment. However, in real-world settings, multiple medical and non-medical challenges affect treatment effectiveness and outcomes [10]. It is thus imperative to see these factors and how they affect the outcome.

This study assessed the outcomes of anti-VEGF therapy in a low-income country. To the best of our knowledge, this will be the first study in Ethiopia and East Africa to analyze the outcomes of anti-VEGF treatment for NvAMD. It has also helped in understanding the scenario in a low-income country regarding the interval between injections and the potential vision gain. Based on the study's results, it may lay the groundwork for potential modifications to the anti-VEGF interval and the number of injections in resource-limited countries.

Research Objective

General objective:

- To determine the anti-VEGF treatment outcome of NvAMD.

Specific objective:

- To determine the change in central macular thickness.
- To determine the change in BCVA from baseline to 12-month post-first injection.
- To determine the number of injections.
- To determine adverse drug effects and complications.

Methods and Subjects

Study design and period

A retrospective cohort study on the anti-VEGF outcome of NvAMD was conducted from September 2021 to August 2023.

Study area

This study was conducted in Nisir Specialized Eye Clinic. A specialized eye center in Addis Ababa, Ethiopia, with an active vitreo-retinal service given by an expert vitreo-retinal surgeon. In addition to vitreo-retinal services, the clinic also offers pediatric ophthalmology, glaucoma, Oculoplastics, and cornea services.

Source population

All patients receiving anti-VEGF injections in the study period.

Study population

All patients receiving anti-VEGF for NvAMD.

Sampling procedure

All consecutive patients with NvAMD who received Anti-VEGF treatment from September 2021 to August 2023.

Eligibility criteria

Inclusion criteria:

- 50 years or older.
- Confirmed diagnosis of NvAMD by OCT and received at least 3 anti-VEGF injections.
- OCT at baseline and at least 4 weeks after last injection with central macular thickness.

Exclusion criteria:

- Change of type of anti-VEGF medication between treatments.
- Lost to follow up within 3 months after the first injection.
- Systemic or ocular conditions that could affect visual function.
- Major cardiovascular event in the past 6 months from first injection.

Outcome variables

Primary outcome:

- Change in central macular thickness is defined as the mean change in CMT from baseline to follow-up.

Secondary outcome

- Improvement in VA.
- Number of injections received.

Data processing and analysis

SPSS Version 27.0, Armonk, NY: IBM Corp., was used for statistical analysis. The data were subjected to statistical analysis using the same version 27.0, and a p-value <0.05 was considered statistically significant.

Data quality

Data were collected from the respective electronic charts by the principal investigator. Data was checked for completeness by the principal investigator and entered into the data analysis software SPSS version 27.

Ethical consideration

The research proposal was submitted to the IRB of the Department of Ophthalmology of Addis Ababa University, School of Medicine. Patient data was held confidential at all times during the research.

Operational definition

Neovascular AMD is defined as choroidal neovascularization (type 1 or type 2) seen on OCT and involving the fovea with associated clinical AMD signs [11].

Result

A total of 159 eyes from 142 study participants were included in this study, with a mean age of 68.7 ± 9.55 years. The majority of our study participants were females (52.8%). The mean number of injections received was 3.42 ± 1.04. The most commonly used type of anti-VEGF was Bevacizumab at 79.2%, followed by Aflibercept (12.6%) and Ranibizumab (8.2%). Around 83.6% of our study participants didn't receive any further anti-VEGF after the initial three doses, while the remaining 16.4% continued to receive anti-VEGF. The injection protocol used in this case was PRN at 16.4%.

The baseline visual acuity was mainly in the range of 20/400-20/630 in 46.5% of cases, improving to 20/50 - 20/200 at both 3- and 12-month post-first-injection (See figure 1). The mean IOP was 16.23 ± 5.44 mmHg at baseline, 16.52 ± 5.03 mmHg at 3 months, and 16.83 ± 5.02 mmHg at 12 months.

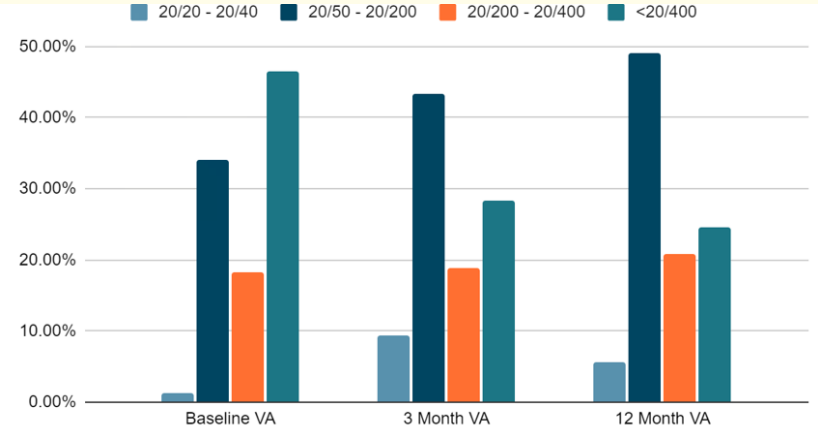

Figure 1: *Visual acuity at baseline, 3 months and 12 months.*

The mean central macular thickness was 358.50 microns (Range: 118 - 600) at baseline, 256.93 microns at 3 months, and 258.55 microns at 12 months. The mean change in CMT after 3 injections was 104.22 microns (95% CI: 77.21, 129.66). Upon seeing the reduction in proportion, the mean reduction in CMT from baseline was 26.41 ± 2.81% (95% CI: 20.96, 32.09) after 3 injections. For those who received more than 3 injections, the 12-month mean change in CMT was 118.42 micron (95% CI: 18.70, 194.25), corresponding to a mean reduction of 33.25 ± 25.38% (95% CI: 20.13, 45.26). There was no statistically significant difference between the two means (p = .149, 95% CI: -64.91, 4.48). No difference in the mean change in macular thickness was observed among the three anti-VEGF agents used in this study (p = 0.28). A macular scar was noted in 23.3% of the study eyes at baseline, increasing to 51.9% at 3 months.

The majority of patients (82.4%, n = 131) received 3 injections. The remaining patients received 4 (1.9%, n = 3), 5 (7.5%, n = 12), 6 (5.0%, n = 8), 7 (3.1%, n = 3), or 8 (0.6%, n = 1) injections. Patients who received 3 injections had a higher proportion (39.3%) in the 20/50 - 20/200 visual acuity category at 3 months after the first injection than in other injection groups. However, there is a great discrepancy in the number of eyes between the three anti-VEGFs.

The majority of our study participants received Bevacizumab (n = 126), followed by Aflibercept (n = 20) and Ranibizumab (n = 13) (See figure 2). In those that took more than 3 injections (17.6%, n = 27), the most common anti-VEGF was again Bevacizumab at 81.4%.

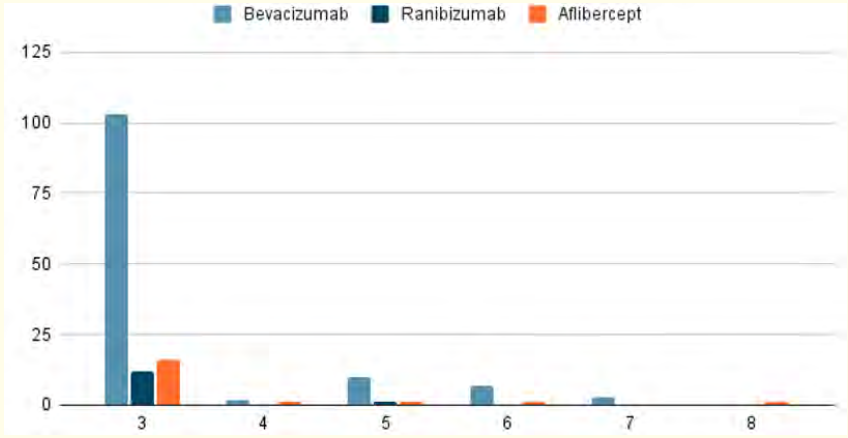

Figure 2: *Anti-VEGF types against number of injections.*

Complications were noted in 4.4% of our study eyes, with the majority being sterile endophthalmitis (57.1%, n = 4), followed by high IOP in 2 study participants (28.6%) and retinal vein occlusion in one eye (14.3%).

Linear logistic analysis showed that third-month visual acuity was correlated only with baseline CMT (p value: 0.001, 95% CI: 0.001, 0.004), while baseline macular scar, type of anti-VEGF, and total number of injections were not correlated (See table 1).

	p-value	95% CI
Sex	.183	(-.106, .592)
Baseline Central Macular Thickness	<0.001	(.001, .004)
Baseline Macular Scar	.765	(-.474, .330)
Type of Anti-VEGF	.924	(-.294, .250)
Total Number of Injections	.180	(-.154, .843)

Table 1: *Linear regression of variables to 3 months visual acuity.*

Discussion

This study sought to assess the efficacy of anti-VEGF therapy for neovascular AMD in a low-income country. Within our study area, there is no government center that provides anti-VEGF therapy, so patients are treated at private ophthalmic centers. The majority of patients fail to continue after the first three intravitreal injections due to financial burden. This study was a retrospective analysis of 159 eyes treated with bevacizumab, ranibizumab, or aflibercept for NvAMD.

Visual acuity was analyzed categorically in this study and showed improvement from 20/400 - 20/630 to 20/50 - 20/200 at both the third month and the 12-month mark after the first injection. Only 16.4% of the study participants had received injections after the initial 3 doses, making comparisons with other research difficult. The mean 3-month reduction in central macular thickness was 104.22 microns. For the 12-month reduction, the mean was 118.42, higher than in other studies [12,13]. However, the reduction from the baseline CMT was only 26.41%.

There was a 26.41% and 33.25% reduction in CMT at 3 months and 12 months, respectively. Amoaku., *et al*. used a good outcome as greater than 75% reduction in intraretinal fluid or CMT or resolution of fluids, while a reduction of 25-75% was considered suboptimal [14]. In this study, macular scar was seen at baseline in 23.3%, while Salman., *et al.* found baseline scarring in 41% [15].

Bevacizumab was the most commonly used anti-VEGF in this study, likely due to its lower cost than the other two anti-VEGFs (Ranibizumab and Aflibercept). There was no statistically significant difference in the 3-month CMT among these three anti-VEGF agents, a finding also reported in other studies [16]. The mean number of injections was 3.42, which is considerably lower than those reported in other studies [17,18]. There were 4.4% cases of sterile endophthalmitis, which occurred after administration of the Avastin biosimilar from an unreliable source. All cases were managed, and inflammation was well treated.

Logistic regression showed that only baseline CMT was correlated with third-month visual acuity, whereas the number and type of injections were not statistically significant.

Conclusion

This study has shown that a significant number of patients receive fewer than 3 anti-VEGF injections; it also shows that, as a proportion, there is minimal reduction in baseline central macular thickness with just 3 injections. This indicates that 3 injections are inadequate. We would also like to emphasize that the 3 initial anti-VEGF injections were not part of the study protocol; rather, the loss to follow-up was due to financial constraints.

Limitation of the Study

One limitation of this study is that visual acuity was analyzed categorically rather than by the gain or loss of visual acuity letters. In addition, we would like to note a discrepancy in the number of eyes across the three anti-VEGF types, which made comparison difficult.

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