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Outcomes of intravitreal Bevacizumab injection on diabetic macular oedema patients of different ethnic groups in a Tertiary hospital setting in KwaZulu-Natal, South Africa: A Retrospective Descriptive Cohort Study.

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Abstract

Background:
To investigate the variation in central macular thickness and visual acuity among different ethnic groups following three intravitreal injections of Bevacizumab at McCord Eye Hospital.

Methods:
A retrospective observational cohort study of patients with diabetic macular edema from different ethnic groups at McCord Eye Hospital. Patients were classified into Black, Caucasian, Coloured, and Indian ethnic groups. Baseline measurements included visual acuity, measured in decimal and reported in LogMAR, and central macular thickness (CMT) measured with optical coherence tomography (OCT). These measurements were taken before three intravitreal Bevacizumab injections spaced six weeks apart, with follow-up measurements two weeks after the third injection. The study compared changes in VA and CMT between ethnic groups and explored the influence of hypertension, dyslipidemia, and ocular prognostic markers on treatment outcomes.

Results:
349 eyes from 204 patients were enrolled. The number of eyes per ethnic group was 170 Indian, 129 Black, 22 Caucasian, and 22 Coloured. Indians showed the least improvement, with a VA change of 0.82 LogMAR (0.15) and a CMT reduction of -90 µm. Caucasian had a VA change of 0.57 LogMAR (0.27) and a CMT of -94 µm. Black experienced a VA change of 0.63 LogMAR (0.24) and CMT of -122 µm. Coloured performed best, with VA change of 0.47 LogMAR (0.34) and CMT of -125 µm (P=0.001). Hypertension and dyslipidemia prevalence in Indian 56%, Caucasian 32%, Black 15%, Coloured 18%.

Conclusion:
The Ethnic groups with the least VA improvement and CMT reduction had the highest prevalence of systemic risk factors and poor prognostic ocular biomarkers, highlighting their significant impact on treatment outcomes.

Recommendations
Diabetic macular oedema requires a multidisciplinary approach to manage systemic risk factors rigorously and early detection of poor prognostic indicators, which will allow for prompt escalation of treatment.

***Keywords**: Diabetic macular oedema, prognostic biomarker.*
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Introduction

Diabetes is a persistent metabolic disorder characterized by insulin resistance or diminished insulin secretion. If diabetes remains uncontrolled for extended durations, it may lead to damage to target organs. The primary organs affected in diabetic conditions include the kidneys, heart, brain, nerves, and eyes.

Diabetes represents the most prevalent metabolic disorder globally. In 2021, approximately 537 million individuals aged 20 to 79 years were affected, accounting for an average of 10% of the global population (1). Projections for 2030 estimate this number will rise to 643 million, equating to approximately 11.3% of the global population (1). The condition impacts all genders, age groups, and ethnicities. It is classified into type 1 and type 2 based on their pathogenesis. However, the clinical manifestations are similar. Notably, type 2 diabetes accounts for 90% of all cases worldwide (2).

The worldwide prevalence of diabetic macular oedema among individuals aged 20 to 70 years is 7,5% (3). The prevalence among type 1 diabetics is 14%, while it is 6.5% among type 2 diabetics; these figures are independent of the duration of the disease. Men and women exhibit similar prevalence rates. Ethnic groups display varying prevalence rates, with the highest global prevalence observed among Black populations and the lowest among Asian populations (3).

Diabetes impacts the eye across multiple layers, each exhibiting different degrees of severity. It may lead to corneal epithelial defects, neovascular glaucoma, cataracts, early vitreous degeneration, diabetic retinopathy, diabetic papillopathy, and diabetic maculopathy.

Diabetic maculopathy is classified into ischemic and exudative types. When it is exudative, it is referred to as diabetic macular oedema. This condition is caused by pericyte loss, leakage from retinal capillaries, and thickening of the basal lamina surrounding retinal vessels. The leaked fluid accumulates between the outer plexiform layer and the inner nuclear layer. As the disease advances, all retinal layers become impacted. These pathological changes result in focal or diffuse areas of ischemia and leukocyte adherence, leading to diabetic macular oedema, as well as an ischemic and inflammatory response (4).

The clinical presentation of diabetic macular oedema is frequently subtle, with patients experiencing a hyperopic shift that is often obscured by presbyopia in elderly individuals. Most patients seek medical attention when the condition is well-established or advanced (5).

The clinical diagnosis and monitoring of diabetic macular oedema can be performed using a slit lamp biomicroscope. While the biomicroscope may assist in the initial diagnosis of diabetic macular oedema, its utility is limited, particularly when there is minimal fluid presence (6).

Optical coherence tomography (OCT) is regarded as an essential tool for diagnosing and monitoring diabetic macular oedema. It is cost-effective, rapid, non-invasive, and provides a detailed visualization of the retinal layers. With the advent of spectral domain and swept source optical coherence tomography, the retinal layers can be observed with greater detail. Disease monitoring through optical coherence tomography is highly accurate. However, it does not directly correlate with the patient's visual acuity (7).

In diabetic macular oedema, optical coherence tomography (OCT) will demonstrate retinal thickening, regions of decreased intraretinal reflectivity within the outer retinal layers, loss of the foveal depression, disorganized inner retinal layers, and hyperreflective foci accompanied by a hyporeflective area posterior to them. OCT can detect minimal changes in retinal thickness and facilitates very early diagnosis of diabetic macular oedema (8).

Other investigations, such as fundus fluorescein angiography, reveal capillary leakage, non-perfused areas, enlarged foveal avascular zones, and assist in treatment planning for laser therapy and in prognosticating visual outcomes (9).

The management of diabetic macular oedema encompasses optimizing glycemic control, alongside the management of hypertension and cholesterol when present. Additional treatment modalities include laser therapy, intravitreal corticosteroids, and vascular endothelial growth factor inhibitors (anti-VEGF) (10).

The management of diabetes with the goal of achieving a haemoglobin A1C(HbA1C) level of less than 7,2%, which decreases the risk of diabetic ocular complications by 76% in individuals with diabetes (11). This approach contributes to delaying the onset and progression of diabetic vascular alterations, which have been associated with diabetic macular oedema (11)(12).

Strict management of hypertension and hypercholesterolemia also diminishes the onset and progression of diabetic microvascular complications (13)(14).

The Argon laser functions by photocoagulating leaking vessels within the retina and ablating photoreceptor cells. This process converts hypoxic cells into anoxic glial cells, thereby decreasing the oxygen demand. The reduction in

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oxygen requirement assists in mitigating the hypoxic drive that stimulates retinal pigment epithelial cells to release vascular endothelial growth factor. Additionally, scarring and ablation at the level of the retinal pigment epithelium facilitate improved oxygen diffusion from the choriocapillaris to the retina (5).

Scatter argon-laser or focal laser therapy is recommended for patients exhibiting clinically significant macular oedema. Administering an aggressive scatter laser in a single session may lead to a temporary exacerbation of the macular oedema. It is generally advantageous to distribute the laser treatment across multiple sessions to mitigate the severity of the oedema (15).

Anti-VEGF is a group of medications that acts as competitive inhibitors of VEGF at the receptor sites and interferes with post-receptor intracellular signaling and RNA transcription (16). In doing so, it inhibits VEGF from stimulating new abnormal vessel formation in the setting of a hypoxic drive. VEGF also induces an inflammatory response by causing expression of vascular cell adhesion molecule 1, which causes leukocyte recruitment, loss of endothelial cell adhesion, and resultant loss of the blood-retinal barrier integrity (16).

Intravitreal anti-VEGF agents approved by the U.S. Food and Drug Administration (FDA) include pegaptanib, ranibizumab, and aflibercept. Bevacizumab has received FDA approval for oncological treatments but is frequently employed off-label in ophthalmology to treat macular oedema. It is approximately five times less potent than aflibercept and ranibizumab (16).

Previous studies have compared aflibercept, ranibizumab, and bevacizumab. Aflibercept demonstrates a superior reduction in macular thickness and enhancement of best corrected visual acuity at one year. By the second year, ranibizumab exhibited improvements comparable to those of aflibercept (21).

Intravitreal ranibizumab was the first FDA-approved anti-VEGF agent. When compared to laser therapy alone, it demonstrated superior improvement in visual acuity and a more significant reduction in macular thickness in patients with diabetic macular oedema (17). The combination of laser treatment and intravitreal ranibizumab is associated with a reduced need for subsequent ranibizumab injections. While the long-term visual outcomes of using ranibizumab alone are generally favorable, frequent injections are often required (17). Over a twelve-month period, in a patient with diabetic macular oedema, treatment with either ranibizumab alone or in combination with laser therapy yielded substantially better results in terms of visual acuity and macular thickness compared to laser therapy alone (18). Additionally, the use of ranibizumab with prompt laser or deferred laser by twenty-four weeks post-injection results in similar outcomes (20).

Three intravitreal injections of Bevacizumab 1.25 mg each, administered at six-week intervals, are presently regarded as the standard practice in state hospitals and have demonstrated superiority over argon laser treatment administered at four-week intervals (19). Patients receiving Bevacizumab exhibit an average gain of nine letters on Early Treatment of Diabetic Retinopathy (ETDRS) charts, compared to a gain of only 2.5 letters from laser therapy alone, in addition to achieving a more substantial reduction in macular thickness, averaging up to 28 micrometers (19).

Intravitreal steroids are frequently indicated for patients with refractory diabetic macular oedema, particularly when there is a higher concentration of proinflammatory mediators compared to VEGF within the eye. These steroids function by inhibiting the synthesis of prostaglandins and leukotrienes, as well as by downregulating proinflammatory cytokines, ICAM-1, and VEGF. Additionally, intravitreal steroids are recommended for patients in whom anti-VEGF therapy is contraindicated, such as those with a history of myocardial infarctions or cerebrovascular accidents.

This study seeks to answer the question of what changes occur in visual acuity and central macular thickness among diabetic macular edema patients of various ethnic backgrounds following three intravitreal injections of bevacizumab 1.25 mg, given six weeks apart, at McCord Eye Hospital. Bevacizumab is the standard treatment for clinically significant macular oedema in state hospitals.

The main objective is to compare central macular thickness and visual acuity across various ethnic groups. The secondary objective is to evaluate how systemic comorbidities such as hypertension, dyslipidemia, and ocular prognostic biomarkers influence treatment outcomes.

Material and methodology

Study design

This study was a retrospective observational cohort study of 36 months. This approach enabled us to have a systematic approach to data collection on patients' baseline workup, treatment outcomes, and risk factor stratification.

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Study Setting and Duration

This investigation was carried out at McCord Eye Hospital, the sole medical facility primarily focused on ophthalmic conditions within the KwaZulu-Natal province. Situated in Durban, this hospital manages complex eye-related cases and serves as the primary teaching institution for registrars (Residents) in the region. The hospital features four full-time operating theatres dedicated to ophthalmic procedures, an outpatient department serving approximately 300 patients daily, and performs around 300 surgical interventions each month. The extensive catchment area and substantial outpatient volume render it an optimal setting for ophthalmic research. The study period spanned from 01 January 2021 to 31 December 2023.

Study population

Patients with diabetic macular oedema, including Black Indigenous South Africans, the Indian population, Coloured individuals, and Caucasians, are treated at McCord Eye Hospital.

Inclusion criteria

- Age range of 18 to 70 years.
- Patients diagnosed with either type 1 or type 2 diabetes.
- Clinical features consistent with diabetic macular oedema, confirmed through slit lamp examination and optical coherence tomography.
- Patients with no cataract, minimal nuclear sclerotic cataracts, or those who are pseudophakic.

Exclusion criteria

- Intraocular surgery was performed three months prior to the injections or concurrently with the administration of the three injections.
- Presence of pre-existing retinal scar, atrophic or dystrophic changes.
- Use of topical corticosteroid eye drops during intravitreal injections.
- Best corrected visual acuity of no perception of light.
- History of ocular trauma.
- Presence of posterior subcapsular cataract.
- Active uveitis.

Sample size

A minimum sample size of 330 eyes is required, considering that the proportion of patients undergoing first-time intravitreal injections is 50%. With a confidence level of 95%, a margin of error of 5%, and a population proportion of 50%.

Sampling method

Purposeful sampling technique

Sampling strategy

All patients with diabetic macular oedema who met the specified inclusion and exclusion criteria were eligible to participate in the study. Patients who received injections at McCord Hospital from 1 January 2021 to 31 December 2023 were administered one injection of bevacizumab every six weeks, with a minimum of three injections. Patients were reassessed two weeks after the third injection.

Data collection method and tools

Records concerning intravitreal treatments with bevacizumab from January 1, 2021, to December 31, 2023, are stored in the hospital's filing room. The bevacizumab records include patient file numbers, which have been matched to the corresponding patient files. Data for the datasheets were obtained from these patient files. Only patient file numbers were utilized to identify individual patient information. Subsequently, the files were secured in the filing room and uploaded to Google Sheets, which was protected by a password.

Data management

Only the researcher, supervisor, and statistician had access to the research data. The information was primarily utilized for the purposes of this study.

Statistical analysis

An analysis of variants, including best corrected visual acuity (VA) and central macular thickness (CMT), was conducted to identify differences among various ethnic groups.

A paired t-test was employed to assess changes before initial injection and two weeks after the final injection.

Logistic regression analysis was utilized to identify factors influencing improvements in VA and CMT, such as hypertension, dyslipidemia, and ocular prognostic biomarkers.

The level of significance was set at a P-value of 0.05. Statistical tool SPSS 29

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Measures to ensure validity

Reduction of bias

The investigator bore the primary responsibility for completing the data sheets. The investigator ensured that the data sheets were accurately completed and maintained strict adherence to inclusion and exclusion criteria.

Selection Bias

Primarily, patients from McCord Eye Hospital in Durban were studied.

Confounding factors

Age, poor glycemic control, and other systemic conditions.

List of associations to be measured

- Visual acuity and central macular thickness
- Number of patients with dyslipidemia and systemic hypertension

Ethical considerations

The study adhered to the principles of the Helsinki Declaration and Good Clinical Practice. Patient race was obtained from the patients' stickers on their files. Patient information was kept confidential and not published. Data sheets only contained patients' file numbers, race, and age. Approval from the National Health Research Database (NHRD) was granted on 23 September 2025, Reference KZ_202509_030. Gatekeeper permission to conduct research at McCord Eye Hospital was obtained from the hospital CEO. Ethical approval from the Nelson R. Mandela School of Medicine Biomedical Research Ethics Committee (BREC) was obtained on 29 September 2025, Reference number BREC/00009141/2025.

Informed consent

Informed consent was waived due to the retrospective nature of the study and the anonymization of patient information, as approved by Nelson R. Mandela School of Medicine Biomedical Research Ethics.

Work plan

Budget: Self-funded for printing Google Sheets; should a hard copy be required?

A University of KwaZulu-Natal (UKZN) statistician helped with guidance.

Patient files were available at McCord Eye Hospital.

Results

A total of 343 eyes of 204 patients fulfilled the minimum eligibility criteria for the study. 98 Indian patients, composed of 36 males and 62 females, with a total of 170 eyes, 78 black patients consisting of 51 females and 27 males, with a total of 129 eyes, 14 caucasian patients consisting of 7 males and 7 females with a total of 22 eligible eyes, 14 Coloured patients, 8 females and 6 males, had 22 eligible eyes for the study. The number of patients with both eyes enrolled in the study was 74 out of the 98 Indian patients, 18 out of the 78 Black patients, 10 out of the 14 Caucasian patients, and 9 out of the 14 Coloured patients. The remainder of the patients only had one eye enrolled in the study.

The median age for the different ethnic groups was 63 years for Indian patients, 65 years for Blacks, 65 years for Caucasians, and 63 years for Coloureds. Indian patients constituted 109 female eyes and 61 male eyes, Black patients 80 female eyes and 49 male eyes, Caucasians 11 female eyes and 11 male eyes, Coloured patients 13 female eyes and 9 male eyes. Systemic conditions such as hypertension and dyslipidemias were assessed. Indian patients with hypertension only were 66 (39%), hypertension and dyslipidemia 95(56%), and 9(5%) had neither hypertension nor dyslipidemia. Black patients with hypertension only were 104 (80%), hypertension and dyslipidemia 19(15%), and 6(5%) had neither hypertension nor dyslipidemia. Caucasian patients with hypertension only were 13 (59%), hypertension and dyslipidemia 7(32%), and 2(9%) had neither hypertension nor dyslipidemia. Coloured patients with hypertension were 17 (77%), hypertension and dyslipidemia 4(18%), and 1(5%) had neither hypertension nor dyslipidemia. Demographic information is summarized in Table 1

Poor Prognostic factors per ethnic group were: Indian patients' eyes 42(25%) had hard exudates, 13 (8%) eyes had large intraretinal cysts, and 23(14%) had macular plaque. Black patient eyes with hard exudates 24(19%) and 4(8%) eyes had large intraretinal cysts, and 3(2%) eyes had macular plaques. Caucasian eyes with hard exudates were 8(36%), and 1(5%) eye had large intraretinal cysts, and 1(5%) eye had macular plaque. Coloured patient eyes showed hard exudates in 8 (36%), 1 (5%) had large intraretinal cysts, and no eyes had macular plaque. A total of 219 eyes were phakic, and 124 were pseudophakic. Ocular prognostic factors and lens status are summarized in Table 1.

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Table 1: Patient Demographics and Ocular Characteristics

	Race	Blacks	Caucasians	Coloured	Indian
Demographic	Number of eyes	129	22	22	170
	Mean age	62.3	68.2	62.5	63.9
	SD	11.39	4.24	2.12	8.49
Age	Median age	65.0	78.0	63.0	63.0
	Female eyes	80 (62%)	11 (50%)	13 (59%)	109 (64%)
Sex	Males eyes	49 (38%)	11 (50%)	9 (41%)	61 (36%)
	HPT	104 (80%)	13 (59 %)	17(77%)	66(39%)
	HPT+Dyslipidaemia	19 (15%)	7 (32%)	4(18%)	95 (56%)
Systemic condition	Non	6 (5%)	2(9%)	1(5%)	9 (5%)
	Hard exudates	24 (19%)	8 (36%)	5 (25%)	42 (25%)
	Macular Plaque	3(2%)	1(5%)	0(0%)	23(14%)
Ocular Prognostic Factor	Large intraretinal Cysts	4 (3%)	1 (5%)	0 (0%)	13 (8%)
	Phakic Eyes	84 (66%)	11 (50%)	12(55%)	112 (66%)
Lens status	Pseudophakic Eyes	45 (34%)	11 (50%)	10 (45%)	58 (34%)

**HPT: Hypertension.* **SD: Standard deviation*

All ethnic groups showed a statistically significant improvement in visual acuity (VA) and a reduction in central macular thickness (CMT) two weeks after three intravitreal injections of bevacizumab 1.25mg, given six weeks apart (p-value 0.001). Black patients had a mean gain in visual acuity of 0.62 LogMar (0.24) and a mean reduction in central macular thickness (CMT) of 123 µm (27%). Caucasian eyes showed a mean improvement in visual acuity of 0.57 LogMar (0.27) and a mean reduction in CMT of 94 µm (23%). Coloured patient eyes showed the greatest mean improvement in VA by 0.47 LogMar (0.34) and mean reduction in CMT of 126µm. Indian eyes showed the least improvement, with a mean VA improvement of 0.82 LogMar (0.15) and a mean CMT reduction of 91µm. See table 2 and table 3

Table 2: Change in visual acuity (VA)

	n	Mean baseline VA	Mean Change in VA	P-value
Black	129	0,258	0,239	<0.001
Caucasian	22	0,235	0,272	<0.001
Coloured	22	0,228	0,339	<0.001
Indian	170	0,237	0,151	<0.001

**n: number of eyes*

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Table 3: Change in central macular thickness (CMT)

	n	Mean Baseline CMT (µ)	Mean Change in CMT (µ)	P-value
Black	129	454,372	122,791	<0.001
Caucasian	22	409,227	94,227	<0.001
Coloured	22	451,227	125,727	<0.001
Indian	170	444,182	90,594	<0.001

Figure 1 illustrates the mean central macular thickness before the patient's eyes have undergone three intravitreal injections of bevacizumab 1.25mg. The eyes from the black population had the highest baseline mean CMT±SD of 454µm±124, followed by the Coloured patient eyes with a mean CMT±SD of 451µm±112. The Indian population being 444µm±125 and the Caucasians 409µm±110. Baseline CMT was not a predictor of response to bevacizumab, as Caucasians had the lowest mean CMT of 315µm, followed by Coloured 325 µm, Blacks 332µm, and then Indians at 353µm.

Figure 1: Mean central macular thickness for different ethnic groups

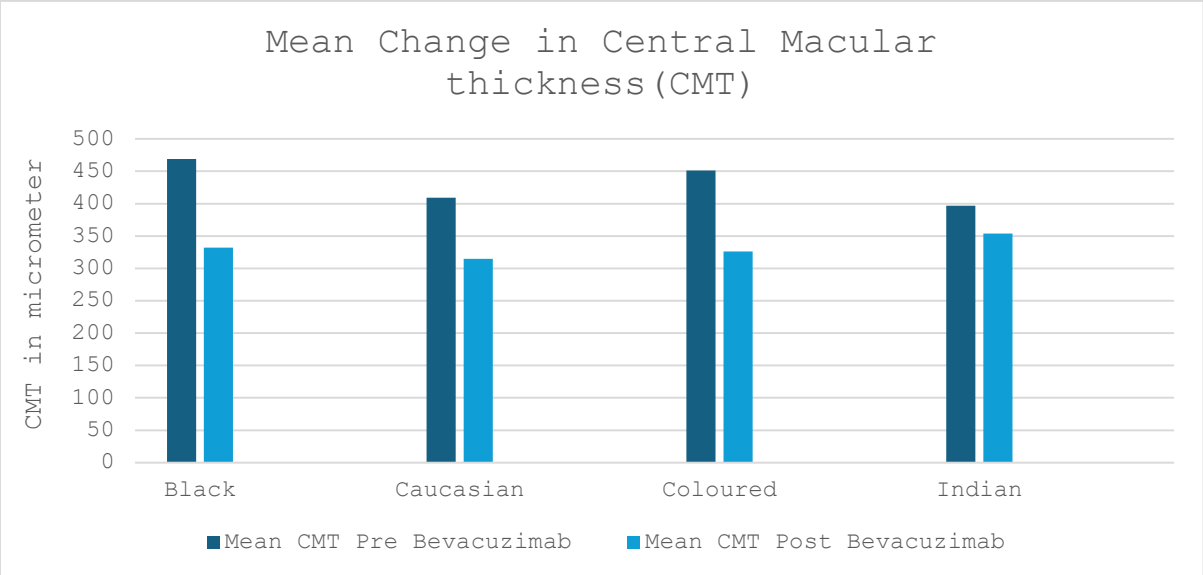

Figure 2 compares the mean VA (measured in decimal and reported in LogMar) before and after three intravitreal injections of Bevacizumab 1.25mg. The Coloured population had the lowest baseline visual acuity of 0.64 LogMar (0.23 decimal), the Caucasian 0.63LogMar (0.24), Indians 0.62LogMar (0.24), and the black population had the highest baseline Visual acuity of 0.59LogMar (0.26). Post Bevacizumab population group with the best visual outcomes were Coloured with a mean visual acuity of 0.24LogMar (0.58), Caucasian 0.29LogMar (0.51), blacks 0.30LogMar (0.50), and Indians 0.41LogMar (0.39).

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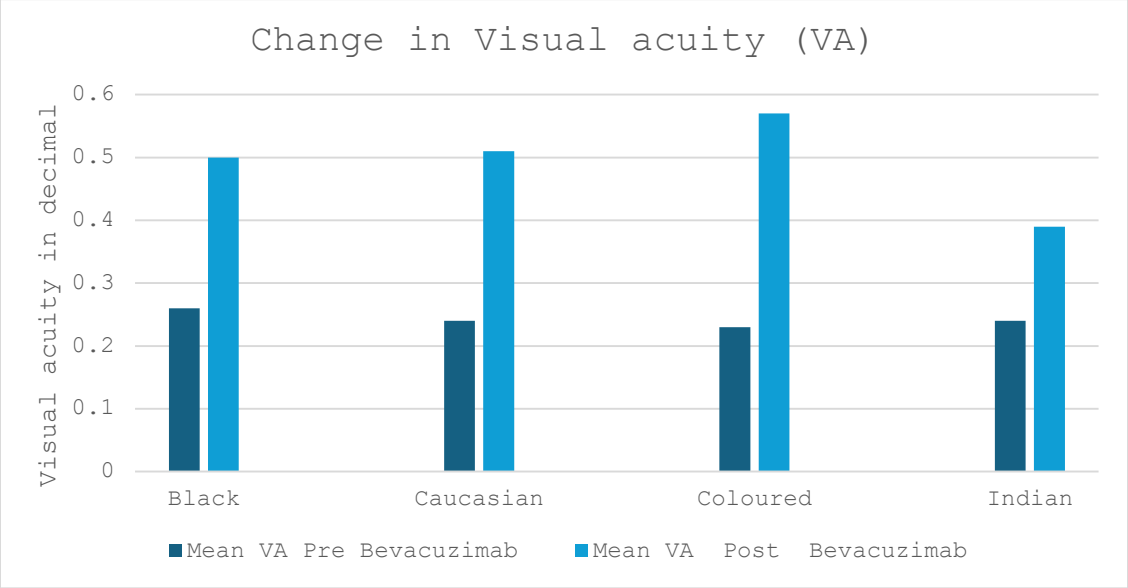
Figure 2: Mean visual acuity for different ethnic groups



Discussion

Diabetic macular oedema is a prevalent complication of diabetes, and the correlation between systemic risk factors and disease progression is frequently overlooked. It is essential to adequately manage these systemic risk factors at the primary healthcare level. The advent of posterior segment imaging modalities, such as Optical Coherence Tomography (OCT), allows for the early identification of poor prognostic biomarkers, enabling timely escalation of treatment. Both systemic risk factors and poor prognostic biomarkers are linked to a diminished reduction of macular oedema and suboptimal visual outcomes, despite treatment with intravitreal anti-VEGF agents like bevacizumab.

The results of this study demonstrated that all ethnic groups experienced a statistically significant improvement in visual acuity (VA) and central macular thickness (CMT) following three intravitreal injections of bevacizumab 1.25mg (p-value of 0.001). Our baseline VA ranged from 0.64 logMar (0.258 decimal) to 0.59 logMar (0.258 decimal). Previous studies evaluating the efficacy of bevacizumab, including the Diabetic Retinopathy Clinical Research. Network (DCRC.net) protocol T and the BOLT study reported baseline VA ranging from 0.30 to 0.60 logMar, have demonstrated that better baseline visual acuity strongly correlates with greater improvement in VA and CMT thickness (18)(19). This study showed that baseline visual acuity alone is not a reliable predictor of treatment outcomes, as systemic conditions and ocular prognostic markers also significantly influence results.

The Indian population in this cohort had the highest percentage of patients with both hypertension and dyslipidemia, whereas the Coloured population had the lowest prevalence of these comorbidities. The systemic differences were reflected in treatment outcomes, as the Indian population showed the least reduction in central macular thickness and the smallest improvement in visual acuity, followed by the Caucasian population. This suggests a strong association between hypertension, dyslipidemia, and diabetic macular edema.

Chung et al. compared the rates of progression of diabetic retinopathy and diabetic macular oedema in 70 patients not on statins and 40 patients on statins (22). The results showed that 23% of patients on statins experienced progression of their diabetic macular oedema, while 48% of patients not on statins had progression; the p-value was 0.08. Based on these findings, the author then suggested that lipid-lowering therapy may have a protective role in the progression of diabetic macular oedema. The study findings are consistent with this observation, as the ethnic groups with the highest

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number of dyslipidemia patients demonstrated a poorer response to intravitreal injection with Bevacizumab.

Similarly, the United Kingdom Prospective Diabetes Study (UKPDS) demonstrated that tight control of hypertension and diabetes reduces the microvascular complications of diabetes, and diabetic macular oedema is one such microvascular complication. Blood pressure control lowered the progression of diabetic microvascular complications by 33% (23). In this study, glycemic control and blood pressure control were not assessed. This is primarily due to resource constraints that limit our institution's ability to perform HbA1C tests on all diabetic retinopathy patients, as this is often measured by the base hospitals managing the patients' diabetes.

Smaller sample-sized studies, like Laheu et al., comparing response to a single intravitreal injection of Bevacizumab 1.25mg in diabetic macular edema patients, have indicated differences in response between black and Indian racial groups, which are of the same demographic as our study. Their study showed that within the first week, the Indian group experienced a small reduction in central macular thickness of 11µm, while the black racial group had a reduction of 61µm. Maximum macular dryness was achieved at 3 weeks. After 6 weeks, as the effects of the intravitreal injection started to diminish, the Indian population had a central macular thickness of 445µm, and the black population measured 467µm; their baseline central macular thickness was 411µm (24). However, systemic and ocular prognostic markers were not specified within these two racial groups.

The study findings were that there was an uneven distribution of ocular poor prognostic markers across racial groups. Hard exudates were present in 25% of Indians, 19% of Blacks, 36% of Caucasians, and 5% of Coloureds. Hard exudates are lipid exudates caused by leaking blood vessels and tend to take longer to resolve. Their effect on vision is largely determined by their location; the closer they are to the fovea, the more profound their impact on visual acuity. Exudates may coalesce and form plaques. Macular plaques were present in 14% of Indians, 2% of Blacks, 5% of Caucasians, and 0% of Coloureds. Macular plaques have a worse prognosis than exudates due to their location, size, association with retinal ischemia, and photoreceptor loss.

Large intraretinal cysts are linked to ischemic changes in the inner retinal layers and loss of photoreceptors. The loss of neuroretinal bridging processes within the cysts indicates a very poor prognosis. In our study, 8% of the Indian population had large intraretinal cysts, followed by the Black population at 3%. The loss of these bridging processes suggests that even after the cysts resolve, there will likely be retinal atrophy and poor vision (25).

Overall, the study findings highlight a strong association between systemic risk factors, ocular prognostic biomarkers, and treatment response in diabetic macular oedema patients. The difference in treatment response among the ethnic groups was largely attributed to the uneven distribution of these systemic risk factors and ocular biomarkers.

Conclusion

Our study demonstrates that intravitreal bevacizumab 1.25mg leads to a statistically significant improvement in both VA and CMT across all ethnic groups after three injections (p-value 0.01). However, the magnitude of the response varied across ethnic groups, possibly due to uneven distributions of systemic risk factors and ocular prognostic biomarkers.

Our findings suggest that baseline visual acuity alone is not a reliable predictor of therapeutic response. Systemic conditions such as hypertension and dyslipidemia appear to play a significant role, as ethnic groups with a higher burden of these conditions demonstrated poorer anatomical and functional outcomes. The uneven distribution of ocular prognostic markers further contributed to variability in treatment responses among the ethnic groups.

The outcomes of this study highlighted the multifactorial nature of diabetic macular oedema and the significance of a holistic approach to managing such patients.

Limitations

This was a single-center study; larger sample sizes and multi-center studies will provide a more accurate picture. The retrospective nature of the study limited the sample size. Diabetic control with HbA1c, hypertension management, and cholesterol levels were not included in the study. Retinal imaging with fundus fluorescein angiography or OCT angiography was not performed to assess ischemic changes.

Recommendation

A multidisciplinary approach involving dietitians, physicians, and ophthalmologists must be adopted when managing diabetic macular oedema patients to ensure optimal treatment outcomes. Tight glycemic control, blood pressure management, and lifestyle modifications should be initiated early. Prompt escalation of treatment, including

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administering a second cycle of bevacizumab, early use of intravitreal steroids, and focal laser treatment for patients with ocular biomarkers on OCT, is essential. More than one vascular endothelial growth factor inhibitor should be made available in government facilities.

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Abbreviations
VA: Visual acuity
CMT: central Macular thickness
Anti-VEGF: Vascular endothelial growth factor inhibitor
ETDRS: Early Treatment of diabetic retinopathy
OCT: Optical Coherence Tomography
NHRD: National Health Research Database
HPT: Hypertension
STDev: Standard deviation
N: Number of eyes
µm: Micrometers

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Author has no conflict of interest.

Authors Contribution
Dr. Isibonile Ndamane-Lead investigator: SP-concepts and design of the study, statistical analysis, result interpretation, literature review, and preparation of the final draft. Conducted statistical analysis, interpreted results, and revised the manuscript.
Dr. Bashir Hadi Laheu -Supervisor: Assisted with editing the script and reviewing data analysis.

Data availability
All data is available on request.

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