ORIGINAL RESEARCH PAPER
Volume - 13 | Issue - 09 | September - 2024 | PRINT ISSN No. 2277 - 8179 | DOI : 10.36106/ijsr
INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

ASSESSMENT OF QUALITY OF LIFE IN PATIENTS OF DIABETIC RETINOPATHY AFTER TREATMENT WITH ANTI-VASCULAR ENDOTHELIAL GROWTH FACTOR (ANTI-VEGF) AND LASER PHOTOCOAGULATION

Ophthalmology

Dr. Arsh Verma* Junior Resident, Department of Ophthalmology, Government Medical College, Amritsar *Corresponding Author

Dr. Saroj Bala Associate Professor, Department Of Ophthalmology, Government Medical College, Amritsar

Dr. Anubha Bhatti Associate Professor, Department Of Ophthalmology, Government Medical College, Amritsar

Dr. Sanjeev Mahajan Professor And Head, Department Of Community Medicine, Government Medical College, Amritsar

Dr. Amit Anant Kukkar Senior Resident, Department Of Ophthalmology, Government Medical College, Amritsar

Dr. Karamjit Singh Professor And Head, Department Of Ophthalmology, Government Medical College, Amritsar

ABSTRACT

A study was done to assess quality of life in patients of diabetic retinopathy after treatment with Anti-VEGF and laser photocoagulation and to evaluate visual, social, and psychometric parameters in patients with diabetic retinopathy. Pretest-Posttest Quasi Experimental Study was conducted in diabetic retinopathy patients undergoing treatment with Anti-VEGF and laser photocoagulation for a period of 1 year in a Tertiary Care Centre. The study participants were divided into two groups: Photocoagulation and Anti-VEGF. After the initial ocular and systemic examinations, each patient was interviewed using the questionnaire (NEI-VFQ 25). The summary score from each domain was added to give a total quality of life score. Regular follow-up at 1-month intervals was done for a period of 3 months. The mean age for the Photocoagulation group was 58.21 years with a standard deviation (SD) of 4.575, while the Anti-VEGF group had a mean age of 59.63 years with an SD of 6.436. The p-value in age, gender, occupation, education, laterality of the eye, duration of diabetes, hypertension, laboratory investigation comparison between the two groups was >0.05% indicating that there was no statistically significant difference between the Photocoagulation and Anti-VEGF groups. The changes in BCVA between both groups over the treatment period was statistically significant, but improvement in Anti-VEGF group was found to be better. Also, there was a significantly greater reduction in CMT in the Anti-VEGF group compared to the Photocoagulation group. The participants treated with Anti-VEGF therapy experienced better outcomes in certain QOL domains (general health, general vision and near activities) compared to those treated with Photocoagulation therapy. Therefore, anti-VEGF therapy should be considered a preferred treatment option for patients with diabetic retinopathy, particularly those with diabetic macular edema requiring intervention.

KEYWORDS

diabetic retinopathy, Anti-VEGF, laser photocoagulation, quality of life

INTRODUCTION

One of the most debilitating complications of diabetes is diabetic retinopathy, a progressive eye condition that can lead to irreversible vision loss if left unmanaged. Diabetic retinopathy is characterized by damage to the retinal blood vessels, a consequence of prolonged exposure to hyperglycemia associated with diabetes mellitus. Vision loss in DR is often attributed to center-involving diabetic macular edema (CDME), affecting 7.5 percent of the diabetic population.[1] Population-based studies have indicated varying prevalence rates of diabetic macular edema (DME) in both type I and type II diabetes patients. In the case of type I diabetes, prevalence ranges from 4.2% to 7.9%, while for type II diabetes, it varies between 1.4% and 12.8% .[2] As diabetes progresses, the incidence of DME increases, with a 5% occurrence within the first five years following diagnosis and a 15% occurrence after 15 years .[3] The condition may cause blindness and a lower quality of life if untreated. The management of diabetic retinopathy and diabetic macular edema involves a multifaceted approach, addressing both the systemic factors and the ocular complications. The available treatment modalities include laser photocoagulation, anti-vascular endothelial growth factor (anti-VEGF) therapies, steroids, and vitrectomy. To address the need for a comprehensive and standardized tool to assess the impact of diabetic retinopathy on quality of life, the American National Eye Institute developed the National Eye Institute Visual Functioning Questionnaire (NEI-VFQ).[4] This study was aimed to study quality of life in patients of diabetic retinopathy after treatment with Anti-VEGF and laser photocoagulation and to assess visual, social, and psychometric parameters in patients with diabetic retinopathy.

MATERIAL & METHODS

Pretest-Post test Quasi Experimental Study was conducted for a period of 1 year. 500 patients of Type 2 diabetes mellitus, who presented to the Tertiary Care Centre were screened over a period of 1 year after taking approval from the ethical committee of the institution. Some form of diabetic retinopathy was found in 372 patients upon fundus examination. Out of 372, 108 patients were found to have clinically significant macular edema. Type 2 diabetes mellitus patients of age > 40 years of any gender with diabetic retinopathy undergoing treatment with Anti-VEGF or Laser Photocoagulation as per routine protocols in the hospital were included in the study. Patients not willing to participate in the study, or with ocular diseases including glaucoma, uveitis, mature cataract, vitreous hemorrhage, retinal detachment, patients with already existing active infection, patients already taking simultaneous procedures for other ophthalmic conditions, patients having cognitive impairment were excluded from the study. After applying inclusion and exclusion criteria 76 patients were enrolled in the study. Informed written consent was taken from the patients in their vernacular language. Seventy-Six (76) patients were randomized into two groups – 38 patients in Laser photo coagulation group & 38 patients in Anti-VEGF group. A thorough systemic examination of each case was done with investigations, namely blood pressure, HbA1c, blood urea, serum creatinine, and lipid profile were done. A detailed clinical examination of both the eyes was done, this included visual acuity, refraction, slit lamp biomicroscopic examination of the anterior segment, intraocular pressure, fundus examination, optical coherence tomography (OCT), Fundus fluorescein angiography (FFA). After the initial ocular and systemic examinations, each patient was interviewed using the questionnaire (NEI-VFQ 25).

The NEI-VFQ 25 assesses quality of life under 11 domains, namely-general health, general vision, ocular pain, near activities, distant activities, social functioning, mental function, role difficulties, dependency, color vision and peripheral vision. The summary score from each domain was added to give a total Quality of Life score. Regular follow-up at 1-month intervals was done for a period of 3 months. After 3 months, each patient was again interviewed with the

same questionnaire. Data analysis was done using licensed SPSS software version 21.0 (Chicago, Illinois). Univariate analyses were done initially and the results were presented with the help of tables, text, bar-diagrams and pie-charts. Descriptive statistics were used to calculate frequencies of categorical variables, and measures of central tendencies and dispersion were used to describe continuous variables. Chi square test was applied to compare the categorical variable and paired and unpaired T test was used to compare the quantitative data.

RESULTS

The mean age for the Photocoagulation group was 58.21 years with a standard deviation (SD) of 4.575, while the Anti-VEGF group had a mean age of 59.63 years with an SD of 6.436. The p-value in age, gender, occupation, education, laterality of the eye, duration of diabetes, hypertension, laboratory investigation, severity of NPDR comparison between the two groups was>0.05% indicating that there was no statistically significant difference between the Photocoagulation and Anti-VEGF groups. After 3 months, the mean change in BCVA from pre-treatment was –0.0558 (SD = 0.14189) in the Photocoagulation group and -0.3595 (SD = 0.19510) in the Anti-VEGF group, with a p-value of 0.0001. This indicates a significantly greater improvement in the Anti-VEGF group compared to the Photocoagulation group. The paired t-test p-value for both groups was 0.0001, indicating that the changes in BCVA between both groups over the treatment period was statistically significant. But improvement in Anti-VEGF group was found to be better. Comparison of mean BCVA between both groups is shown in TABLE-1

Table 1: Comparison Of Bcva (logmar) Between Both Groups

BCVA (LogMAR)	Photocoagulation		Anti-VEGF		'p' value
	Mean	SD	Mean	SD	
BCVA (LogMAR) at baseline	0.82	0.14685	0.83	0.17	0.755
BCVA (LogMAR) at 3-months	0.76	0.18928	0.47	0.23	0.0001
Change in BCVA (LogMAR)	-0.05	0.14189	-0.36	0.19	0.0001
p-value (paired t test)	0.0001		0.0001		

Abbreviation: BCVA- best corrected visual acuity Anti-VEGF- Anti vascular endothelial growth factor SD- Standard deviation

After 3 months, the mean post-operative CMT was 333.84 µm (SD = 94.570) in the Photocoagulation group and 276.05 µm (SD = 83.450) in the Anti-VEGF group, with a p-value of 0.006. This suggests a significantly greater reduction in CMT in the Anti-VEGF group compared to the Photocoagulation group. The mean change in CMT from pre-operative was -162.37 µm (SD = 103.67) in the Photocoagulation group and -241.42 µm (SD = 92.03) in the Anti-VEGF group, with a p-value of 0.001. This indicates a significantly greater reduction in CMT in the Anti-VEGF group compared to the Photocoagulation group. The paired t-test p-value for both groups was 0.0001, indicating that the changes in CMT within each group over the treatment period was statistically significant. Comparison of CMT between both groups is shown in Table 2

Table 2: Comparison Of Cmt(central Macular Thickness) Between Both Groups

CMT	Photocoagulation		Anti-VEGF		p-value
	Mean	SD	Mean	SD	
CMT at Baseline	496.47	78.56	517.47	90.15	0.283
CMT at 3 Months	333.84	94.57	276.05	83.45	0.006
Change in CMT	-162.37	103.67	-241.42	92.03	0.001
'p'-value (paired 't' test)	0.0001		0.0001		

Abbreviation: CMT- Central macular thickness Anti-VEGF- Anti vascular endothelial growth factor SD- Standard deviation

The p-values indicated statistically significant differences in QOL domains i.e. General health (p = 0.018), General vision (p = 0.037), and Near activities (p = 0.030) between the two groups. These findings suggest that participants treated with Anti-VEGF therapy experienced better outcomes in these specific QOL domains compared to those treated with Photocoagulation therapy. However, other domains did not show significant differences, indicating similar impacts on QOL between the two treatment modalities in those aspects. Comparison of post treatment QOL score between both groups is shown in Table 3.

Table 3: Comparison Of Post Treatment Qol Domain Score Between Both Groups

Domain	Photocoagulation		Anti-VEGF		p-value
	Mean	SD	Mean	SD	
General health	63.947	18.5417	73.618	16.3853	0.018
General vision	41.45	15.85	48.29	11.984	0.037
Ocular pain	81.25	17.3765	75.921	23.3613	0.263
Near activities	55.9418	23.03759	65.8332	15.21859	0.030
Distance activity	59.8463	21.49189	62.1489	16.44543	0.601
Social functioning	65.8558	26.41235	71.9297	16.49207	0.233
Mental health	58.1579	31.02791	66.2939	26.86588	0.226
Role difficulties	54.2434	28.30149	66.7105	28.06607	0.058
Dependency	62.0066	30.76933	71.2174	29.64498	0.188
Driving	53.9212	16.43538	63.0213	24.71502	0.220
Color vision	88.158	18.1369	83.553	23.4494	0.342
Peripheral vision	63.816	27.0743	64.474	25.0887	0.913
Composite score	62.48	14.14	67.73	12.59	0.092

Abbreviation: Anti-VEGF- Anti vascular endothelial growth factor SD- Standard deviation QOL-Quality of life

DISCUSSION

Diabetic retinopathy (DR) is a leading cause of visual impairment and blindness globally, particularly in the working-age population.[5] The management of DR and its complications, such as diabetic macular edema (DME), has evolved significantly with the advent of anti-vascular endothelial growth factor (anti-VEGF) therapies. These therapies have shown superior outcomes in terms of anatomical and functional improvements compared to traditional laser photocoagulation .[6] However, the impact of these treatments on the quality of life (QOL) of patients with DR has been a subject of debate.

In this study, we evaluated the QOL in patients with diabetic retinopathy after treatment with either anti-VEGF therapy or laser photocoagulation. We utilized the National Eye Institute Visual Functioning Questionnaire (NEI-VFQ) to assess various domains of QOL, including general health, general vision, ocular pain, near and distance activities, social functioning, mental health, role difficulties, dependency, color vision, and driving.

The mean change in BCVA from pre-treatment showed significantly greater improvement in the Anti-VEGF group compared to the Photocoagulation group. These findings suggest that patients treated with Anti-VEGF experienced superior visual acuity outcomes compared to those undergoing laser photocoagulation therapy. This is consistent with results reported in the BOLT trial.[7] The superior visual outcomes observed in the Anti-VEGF group of the current study may be attributed to the specific mechanisms of action, its effectiveness in managing macular edema and reducing risk of vision loss. Our results indicate that patients treated with anti-VEGF therapy had statistically significant improvements in central macular thickness (CMT) compared to those treated with laser photocoagulation. This reduction in CMT correlated with improvements in visual acuity, which were significantly better in the anti-VEGF group. These findings are consistent with previous studies that have demonstrated the superior efficacy of anti-VEGF agents in reducing DME and improving visual outcomes.[8,9]

Moreover, our study showed that patients treated with anti-VEGF therapy reported better QOL scores in certain domains, specifically general health, general vision, and near activities, compared to those treated with laser photocoagulation. These findings suggest that anti-VEGF therapy not only provides better anatomical and functional outcomes but also enhances the subjective perception of visual function and overall well-being among patients with diabetic retinopathy. Similar findings have been reported in the studies done by Garweg et al[10] and Wang et al.[11]However, it is important to note that both treatment modalities were comparable in terms of their impact on other QOL domains such as ocular pain, distance activities, social functioning, mental health, and role difficulties. This suggests that while anti-VEGF therapy may offer specific advantages in certain aspects of QOL, both treatments have similar overall impacts on patient-reported outcomes.

CONCLUSION

In conclusion, our study highlights the significant improvements in anatomical and functional outcomes achieved with anti-VEGF therapy compared to laser photocoagulation in patients with diabetic retinopathy. These improvements are accompanied by enhanced quality of life in domains related to general health, general vision, and near activities. These differences in QoL outcomes may be attributed to the superior visual acuity outcomes and better reduction in central macular thickness observed in the Anti-VEGF treatment group. However, the complex interplay between treatment mechanisms, visual outcomes, and the multifaceted aspects of quality of life warrants further investigation. The study's findings underscore the importance of incorporating comprehensive assessments of quality of life, alongside traditional clinical and visual outcomes, in the management of diabetic retinopathy. By addressing the patient's overall well-being and preferences, clinicians can optimize the personalized care and improve the quality of life for individuals affected by this chronic and debilitating condition. Therefore, anti-VEGF therapy should be considered a preferred treatment option for patients with diabetic retinopathy, particularly those with diabetic macular edema requiring intervention.

Limitations

This study has several limitations. First, the sample size was relatively small, which may limit the generalizability of our findings. Second, the study duration was short-term (3 months), and longer-term follow-up is necessary to assess the sustainability of treatment effects on QOL. Third, there may be inherent biases associated with the retrospective nature of data collection and questionnaire-based assessments. Lastly, the study did not assess cost-effectiveness, which is an important consideration in resource-limited settings.

Recommendations

Based on our findings, we recommend conducting larger prospective studies with longer follow-up periods to further elucidate the long-term effects of anti-VEGF therapy on both clinical outcomes and quality of life in patients with diabetic retinopathy. Additionally, studies assessing the cost-effectiveness and patient satisfaction with different treatment modalities would provide valuable insights into optimizing the management of diabetic retinopathy.

Conflict Of Interest

The authors declare no conflicts of interest.

REFERENCES

1. Moradi A, Sepah YJ, Sadiq MA, Nasir H, Kherani S, Sophie R, et al. Vascular endothelial growth factor trap-eye (Aflibercept) for the management of diabetic m
2. Lee R, Wong TY, Sabanayagam C. Epidemiology of diabetic retinopathy, diabetic macular edema and related vision loss. Eye Vis (Lond)2015;2:17.
3. Aiello LM. Perspectives on diabetic retinopathy. Am J Ophthalmol2003;136 (1):122-35.
4. McClure TM, Choi D, Becker T, Cioffi GA, Mansberger SL. The effect of visual impairment on vision related quality of life in American Indian/ Alaska natives. Ophthalmic Epidemiol 2009;16(2):128-35.
5. American Diabetes Association. Standards of medical care in diabetes—2016. Diabetes Care. 2016;39(Suppl 1)
6. Early Treatment Diabetic Retinopathy Study Research Group. Photocoagulation for diabetic macular edema. Early Treatment Diabetic Retinopathy Study report number 1. Arch Ophthalmol. 1985;103:1796-1806.
7. Michaelides M, Kaines A, Hamilton RD, Fraser-Bell S, Rajendram R, Quhill F, et al. A prospective randomized trial of intravitreal bevacizumab or laser therapy in the management of diabetic macular edema (BOLT study) 12-month data: report 2. Ophthalmology. 2010;117(6):1078-1086.e2.
8. Mitchell P, Bandello F, Schmidt-Erfurth U, et al. The RESTORE study: ranibizumab monotherapy or combined with laser versus laser monotherapy for diabetic macular edema. Ophthalmology. 2011;118:615-625.
9. Nguyen QD, Brown DM, Marcus DM, et al. Ranibizumab for diabetic macular edema: results from 2 phase III randomized trials: RISE and RIDE. Ophthalmology. 2012;119:789-801.
10. Garweg JG, Stefanickova J, Hoyng C, Schmelter T, Niesen T, Sowade O, et al. Vision-related quality of life in patients with diabetic macular edema treated with intravitreal aflibercept: the AQUA study. Ophthalmology Retina. 2019;3(7):567-75.
11. Wang Q, Cai H, Xu D, Cui L, Zhang Y, Chen M. Pars plana vitrectomy assisted by intravitreal injection of conbercept enhances the therapeutic effect and quality of life in patients with severe proliferative diabetic retinopathy. Am J Transl Res. 2022 Feb 15;14(2):1324-1331.