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Original Research Article

The impact of diabetic retinopathy on patients' quality of life: A comprehensive evaluation

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Abstract

Background: To assess the quality of life in patients with diabetic retinopathy using NEI-VFQ 25 questionnaire, with comparison to patients without DR.
Aim & Objective: The Impact of Diabetic Retinopathy on patients' Quality of Life: A comprehensive evaluation.
Materials and Methods: This prospective study enrolled a total of 150 diabetic patients with 100 patients having diabetic retinopathy as case group and 50 patients with no diabetic retinopathy changes as control group. Quality of life was then compared between these two groups as well as with the severity of diabetic retinopathy using NEI-VFQ 25 questionnaire.
Results: Of the 150 patients, 49.3% were females and 50.7% were males. The mean age of the patients in case and control group was 60.58±8.12 and 64.48±8.76 years respectively. Majority of the sub scales had significantly higher ($p<0.001$) score in control group as compare to case group. The driving sub-scale had the lowest mean in both cases (36.57±40.76) as well as the control (52.14±46.84) group followed by the general health sub-scale (67.50±18.29 in the case group and 75 ± 0 in control group) and general vision subscale (67.5± 18.29 in case group and 76.5±5.99 in control group).
Conclusion: The quality of life is poor in patients with diabetic retinopathy. It further deteriorates with the increased severity of diabetic retinopathy.

Keywords: Quality of life, Diabetic retinopathy (DR), Diabetes mellitus (DM), Visual impairment.

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1. Introduction

Eye health is integral to achieving the sustainable development goals and universal health coverage. Diabetes mellitus is one of the most important public health challenges of the 21st century and is considered by many as a global epidemic.[1] The prevalence of diabetes mellitus for all age groups worldwide was estimated to be 2.8% in 2000 and 4.4% in 2030. India is leading the world with 21.7% prevalence of diabetic patients.[2]

Diabetes, which is a lifestyle disorder, has now evolved into an epidemic disease affecting even the young adults throughout the world. If not controlled at the earliest, it will progress and eventually affect every organ in the body leading to increased morbidity and eventually mortality. Diabetes is strongly associated with microvascular and macrovascular complications including retinopathy, nephropathy, neuropathy, ischemic heart disease, peripheral vascular disease, and cerebrovascular disease resulting in organ and tissue damage.

Diabetic retinopathy is a well-known complication of long-standing and poor glycemic controlled diabetics seen in 24% of diabetic patients.[3] Diabetic retinopathy accounted for 1.07% of blindness and 1.25% of moderate to severe visual impairment in 2015.[4] Visual impairment due to diabetic retinopathy and the costs associated with its treatment hugely impact the quality of life and impose a heavy financial burden on society.[5] In this context, psychological distress as well as psychological disorders like anxiety and depression could emerge, further deteriorating patients' quality of life.[6-8]

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It is necessary to view the quality of life of patients with diabetic retinopathy from two closely linked perspectives, in which we include the aspect of life with restrictions in connection to general compensation of Diabetes Mellitus and the aspect of life with the visual affliction with all its consequences on the overall quality of life. Several questionnaires can be employed in the evaluation of the potential impact of Diabetic Retinopathy on patients' quality of life, including The National Eye Institute Visual Function Questionnaire-25 (NEI VFQ- 25), the VF -14 Questionnaire, the Beck Anxiety Inventory (BAI), the Retinopathy - Dependant Quality of Life (RetDQol), the Audit of Diabetes Dependant Quality of Life (ADDQoL).

The NEI-VFQ-25 is a reliable, self-administered general questionnaire designed to measure vision function in patients with chronic eye diseases like diabetic retinopathy, cataracts, macular edema, glaucoma, etc. This has an edge over other measures such as VFQ-14 which is more specific to assess outcomes associated with cataract and its treatment.[9] VFQ-25 has been shown superior to visual acuity in measuring the vision-related quality of life since it encompasses mental and social impact in addition to vision-related activities.[10] It also addresses the three components recommended by the World Health Organisation's International Classification of Functioning Disability and Health (WHO-ICF) for measuring health-related consequences of a disease, that is, impairment, activity limitation and participation restriction. The questionnaire consists of 25 questions[11] focusing on 7 basic areas, assessing the following-

The general condition of health and sight, problems in activities using near and distant vision, problems in peripheral and colour vision, social function, psychological problems, experience and reaction to problems due to affliction of vision.[12] Response to each item measures a score from 0 to 100 according to the level of difficulty faced, in which 100 indicates the best possible and 0, the worst possible function.

2. Materials and Methods

A prospective study was conducted in the outpatient section of the Regional Institute of Ophthalmology, Amritsar, India from January 2023 to December 2023 for one year after getting due approval from the Ethics committee (Institutional Review Board) in adherence with the Declaration of Helsinki.

2.1. Inclusion criteria

Patients > 18 years of age with Type I or Type 2 Diabetes mellitus who were ready to give consent.

2.2. Exclusion criteria

Patients with a significant grade of cataract who were graded as per LOCS - >grade 3 nuclear sclerosis, grade 3 posterior subcapsular cataract

Patients with psychiatric illness.

Patients with corneal blindness, glaucoma, ARMD, CRAO, CRVO, and optic neuritis.

A total of 150 diabetic patients were enrolled in the study with 100 patients as cases with diabetic retinopathy and 50 patients without any clinically detectable retinopathy changes as control. Random blood sugar and glycosylated Hb were measured to identify diabetes. A participant was considered to have DM if any of the following criteria were met:

1. Had a history of DM and was being treated with oral hypoglycemic medication, insulin, or diet alone.
2. Had fasting blood glucose >126mg/dl.
3. Had a random blood sugar of ≥200mg/dl
4. HbA1c measured as 6.5% or higher.
5. Symptoms of diabetes.
6. Had a 2-hour plasma glucose level of >200mg/dl after a 75gm oral glucose tolerance test.

Subjects who were diagnosed with diabetes before the age of 30 years and were dependent on insulin were classified as having Type 1 DM. The rest were classified as Type 2 DM. The ocular examination included measurement of BCVA, colour vision, intraocular pressure, slit lamp biomicroscopy, and dilated fundus examination.

BCVA was obtained using a Snellen chart at a distance of 6 meters and results were converted into a Logarithm of the Minimum angle of resolution (LogMAR) acuity for standardization. Colour vision was assessed using an Ishihara chart. IOP was measured using a noncontact tonometer. Dilated fundus examination was done by indirect ophthalmoscopy using 20D LENS.

DR was assessed by masked standardization grading of stereoscopic photographs from 7 standard fields. DR in each eye was graded using ETDRS classification as:

1. Mild non-proliferative Diabetic retinopathy
2. Moderate non-proliferative Diabetic retinopathy
3. Severe non-proliferative Diabetic retinopathy
4. Very Severe non-proliferative Diabetic retinopathy
5. Proliferative diabetic retinopathy

These patients were made to undergo SD-OCT to confirm the presence of clinically significant macular edema in association with diabetic retinopathy. The systolic and diastolic blood pressure was measured using a sphygmomanometer. The venous blood sample was obtained to measure blood glucose levels, glycosylated haemoglobin, serum urea, serum creatinine, and total lipid profile. Various comorbidities like hypertension, obesity, cardiac history, stroke, nephropathy, and neuropathy were noted. The details of diabetes like its duration, and treatment taken were also recorded.

A written consent was taken from the patients enrolled in the study. NEI- VFQ-25 questionnaire was administered in the native language to each of the participants in the OPD

premises. All items were scored using standard scoring procedures, with 100 being the maximum and zero being the minimum score.

3. Results

The present study included 150 diabetic patients with 100 having diabetic retinopathy as the case group and 50 patients without diabetic retinopathy as the control group. The data regarding demographic characteristics, diabetes-related appraisals, associated co-morbidities, and biochemical markers are shown in **Table 1**- **Table 4** respectively. The type of diabetic retinopathy including treatment details and ophthalmic considerations are shown in **Table 5** and **Table 6**.

3.1. Statistical analysis

The data analyses were conducted using SPSS statistical software (version 22.0). Quantitative variables were expressed as the mean (standard deviation) whereas qualitative variables were expressed as absolute or relative frequencies. Unpaired T-tests and analysis of variance (ANOVA) were used to compare the means of various variables. P value was considered significant if it is <0.05 and highly significant if it is <0.001.

Table 1: Demographic details of the study groups

		Cases (100)	Control (50)
Gender	Male	51 (51%)	25 (25%)
	Female	49 (49%)	25 (25%)
Age	MEAN	60.58±8.12	64.48±8.76
Working	Yes	23 (23%)	12 (24%)
	No	77 (77%)	38 (76%)
Income	<15k	18 (18%)	4 (8%)
	15K-30K	68 (68%)	40 (80%)
	>30K	14 (14%)	6 (12%)
Education	<8th standard	56 (56%)	23 (46%)
	8th -10th standard	36 (36%)	19 (38%)
	Upto12th standard	6 (6%)	2 (4%)
	graduate	2 (2%)	6 (12%)
Smoking	Yes	12 (12%)	5 (10%)
	No	88 (88%)	45 (90%)
Alcoholic	Yes	21 (21%)	11 (22%)
	No	79 (79%)	39 (78%)

A total of 150 diabetic patients were enrolled in the study. The sex distribution was almost the same with 49.3% of females and 50.7% of males. The majority of the patients (86.7%) were from rural areas. The mean age of patients in the case and control group was 60.58±8.12 and 64.48±8.76 years respectively. Of the 150, 5.3% of patients were graduate. Rest 94.7% of patients were undergraduates. Most of the patients were from the lower middle class with monthly income between 15k-30k. Only 12% of patients in the case group and 10% patients of control group gave a history of smoking whereas 21% of patients in case group and 22% in control group had a history of alcohol intake.

Table 2: Diabetes-related appraisals

		Cases	Control
1. Random blood glucose	MEAN	196±18.7	168±20.2
2. Hba1c	MEAN	9.32±1.18	7.6±.22
. Type of diabetes	Type 1	6 (6%)	2 (4%)
	Type 2	94 (94%)	48 (96%)
Duration of diabetes	MEAN	6.15± 3.46	4.04±1.77
Treatment taking	Oral hypoglycemic agents	92 (92%)	48 (96%)
	Insulin	8 (8%)	2 (4%)
	Adjuvant ayurvedic medication	23 (23%)	6 (12%)

The mean RBS in the case group was 196±18.7 and in the control group was 168± 20.2 mg%. The mean HbA1C in case group was 9.32± 1.18 and in the control group was 7.66± .286. The mean duration of diabetes was 6.15± 3.46 years among cases and 4.04±1.77 among the control group. Of 150 patients, 93.3% patients were on oral hypoglycemic agents whereas 6.7% were taking insulin therapy.

Table 3: Biochemical markers

		Cases	Control
Mean Random blood glucose		196±18.7	168±20.2
Mean HbA1C		9.32±1.18	7.6±.22
Mean Blood pressure	Systolic	152±16.2	144±12.4
	Diastolic	96±6.2	92=/-4.4
Mean Blood urea		20.46±4.64	18.42±2.23
Mean Serum creatinine		.84±.54	.80±.32
Mean total cholesterol		238.26±32.8	220.68±14.8

The mean blood urea, mean serum creatinine and the mean total cholesterol are as shown above in **Table 3**.

Table 4: Diabetic retinopathy related aspects

		Out of 100 DR Cases
Type of Diabetic Retinopathy	Mild NPDR	51 (51%)
	Moderate NPDR	32 (32%)
	Severe NPDR	12 (12%)
	Very Severe NPDR	1 (1%)
	PDR	4 (4%)
Associated CSME	Yes	14 (14%)
	No	86 (86%)
History of PRP	Yes	5 (5%)
	No	95 (95%)
History of Anti-vegf	Yes	15 (15%)
	No	85 (85%)

Among the cases, 51% of patients had mild NPDR, 32% of patients had moderate NPDR, 12% of patients had severe NPDR, 1% had very severe NPDR and 4% had PDR. A total of 14% patients with diabetic retinopathy had associated CSME. Anti-VEGF was given in 13% of patients whereas PRP was done in 4% patients of case group.

Table 5: Ophthalmic considerations

		Cases	Control
Visual acuity	LogMAR 0.0 - LogMAR 0.5	81 (81%)	50 (100%)
	LogMAR 0.6- LogMAR 1.0	13(13%)	nil
	<LogMAR 1.0 - HM	5 (5%)	nil
	Only PL +	1 (1%)	nil
Colour vision	Normal	86 (86%)	50 (100%)
	Abnormal	14 (14%)	nil

Table 5 showing the visual acuity status among the study group. 81% of the cases and 100% of the control group had visual acuity between LogMAR 0.0 and LogMAR 0.5. Only 6% of patients in the case group had visual acuity less than LogMAR 1.0. The colour vision was affected in 14% of patients in the case group only.

Regarding the distribution of NEI-VFQ 25 scores among the case group, the majority of the sub-scale scores were more than 70 whereas it was 100 among the control group. Among the sub-scales, peripheral vision had the highest mean (86.73 ± 22.76 in the case group and 100 in the control group) followed by colour vision (85.35 ±24.22 in the case group and 100 in the control group). The driving sub-scale had the lowest mean in both cases (36.57 ±40.76) as well as the control (52.14 ±46.84) group followed by the general health sub-scale (67.50 ±18.29 in the case group and 75 ± 0 in control group) and general vision subscale (67.5 ± 18.29 in case group and 76.5 ±5.99 in control group). The ocular pain had a mean of 71.5 ±8.71 in the case group and 84.5 ±12.2 in the control group. The composite score had a higher mean in the control group (90.96 ±2.19) than in the case group (77.28 ± 18.89).

Table 6: NEI-VFQ -25 score in each group

		Mean Score	P value
General Health	Cases	67.50±15.28	0.001
	Control	75.00±.00	
General vision	Cases	67.50±18.29	0.02
	Control	76.50±5.99	
Ocular pain	Cases	71.5±8.71	0.001
	Control	84.5±12.25	
Near vision	Cases	71.37±18.82	.001
	Control	75.00±0.00	
Distance vision	Cases	71.32±22.74	.001
	Control	78.50±12.78	
Colour vision	Cases	85.35±24.22	0.001
	Control	100.0±.00	
Peripheral vision	Cases	86.73±22.76	0.001
	Control	100.0±.00	
Driving	Case	36.57±40.76	0.001
	Control	52.14±46.84	
Social functioning	Case	81.00±24.00	0.001
	Control	100±.00	
Mental health	Case	72.74±21.78	0.001
	Control	99.62±1.49	
Role difficulty	Case	76.5±19.07	0.001
	Control	100.00±.00	
Dependency	Case	84.75±21.87	0.001
	Control	100.00±.00	
Composite score	Case	77.28±18.89	0.001
	Control	90.96±2.199	

Table 7 showing the mean NEI-VFQ 25 subscales' score in different grades of diabetic retinopathy. As the severity of retinopathy increases, the mean subscale score decreases significantly.

Table 7: Comparison of NEI-VFQ score and with severity of diabetic retinopathy in case group

Mean Score	Mild NPDR Right/ Left		Moderate NPDR		Moderate NPDR with CSME		Severe NPDR		Severe NPDR with CSME		Very Severe NPDR with CSME		PDR		PDR with CSME	P value
General Health	74.47 ±3.64	74.48 ±3.60	71.74 ±11.44	70.83 ±9.51	46.43 ±9.44	40.00 ±13.69	65.63 ±12.39	59.09 ±16.85	43.75 ±12.50	31.25 ±12.50	25 ±0.00	25 ±0.00	25.00	25.00	25.00	0.001
General vision	76.59 ±6.17	76.56 ±6.11	71.73 ±11.44	69.79 ±12.72	42.85 ±12.19	40.00 ±13.69	65.62 ±12.93	56.81 ±19.6	31.25 ±12.50	25.00 ±0.00	25 ±0.00	0.00	25.00	25.00	12.5 ±17.67	0.001
Ocular pain	75.00 ±.000	75.00 ±0.00	73.91 ±5.21	71.87 ±8.44	57.14 ±12.19	60.00 ±13.69	75.00 ±.00	70.45 ±10.11	56.25 ±12.50	50.00 ±0.00	50.00	50.00	50.0	50.00	50.00 ±0.00	0.001
Near vision	81.38 ±11.018	80.72 ±10.61	73.91 ±11.86	72.91 ±14.58	50.00 ±14.43	50.00 ±17.67	65.62 ±12.93	61.36 ±13.05	37.50 ±14.43	25.00 ±0.00	12.50	25.00	25.0	12.50	37.50 ±0.00	0.001
Distance vision	85.08 ±9.97	84.87 ±10.12	73.54 ±16.40	72.56 ±14.83	44.04 ±10.45	36.66 ±12.64	66.66 ±14.08	57.57 ±20.56	31.25 ±12.50	25.0 ±0.00	0.00	25.00	25.0	0.00	25.00	0.001
Colour vision	100 ± 0.00	99.47 ±3.60	86.95 ±16.63	83.69 ±19.37	46.42 ±9.44	45.00 ±11.18	81.25 ±11.57	68.18 ±25.22	37.50 ±14.43	31.25 ±12.50	25.00	25.00	25.0	25.00	25.00	0.001
Peripheral vision	100 ±0.00	99.46 ±3.64	88.04 ±14.82	86.95 ±14.82	57.14 ±18.89	50.00 ±17.67	81.25 ±11.57	70.45 ±24.54	50.00 ±28.86	37.50 ±25.00	25.00	25.00	25.0	25.00	25.00	0.001
Driving	53.006 ±40.35	53.63 ±40.15	28.61 ±38.65	21.86 ±36.58	7.14 ±12.19	20.00 ±20.91	19.78 ±36.70	14.39 ±32.07	6.25 ±12.50	6.25 ±12.50	0.00	0.00	0.0	0.00	0.00	0.001
Social functioning	91.75 ±11.44	91.40 ±11.57	87.50 ±14.59	82.81 ±21.43	42.85 ±12.19	50.00 ±17.67	78.12 ±8.83	65.90 ±23.11	31.25 ±12.50	25.00 ±0.00	25.00	25.00	25.00	25.00	25.00	0.001
Mental health	82.712 ±9.50	82.03 ±10.52	72.82 ±19.46	70.05+/21. 49	38.38 ±12.71	42.48 ±20.44	67.96 ±16.17	61.92 ±17.11	35.92 ±12.87	29.68 ±9.37	25.00	25.00	34.37 ±13.25	25.00	34.37 ±13.25	0.001
Role difficulty	84.30 ±6.62	84.11 ±6.69	79.34 ±9.68	77.08 ±14.58	50.00 ±20.41	50.00 ±17.67	76.56 ±4.41	67.04 ±17.91	37.50 ±14.43	31.25 ±12.50	25.00	25.00	25.0	25.00	37.50 ±17.67	0.001
Dependency	97.34 ±7.79	96.87 ±8.35	84.78 ±14.57	83.33 ±15.92	53.57 ±17.25	50.00 ±17.67	78.12 ±8.83	70.45 ±18.76	43.75 ±23.93	37.50 ±14.43	25.00	25.00	37.5 ±17.67	25.00	37.50 ±17.67	0.001
Composite score	87.44 ±3.36	87.23 ±3.49	79.53 ±11.05	77.48 ±13.40	48.05 ±11.85	45.78 ±12.17	75.43 ±7.82	65.89 ±18.90	38.83 ±14.51	32.41 ±7.25	21.00	25.00	29.48 ±.72	21.50	30.90 ±8.34	0.001

4. Discussion

DR is one of the leading causes of preventable visual impairment and blindness worldwide, despite existing accurate diagnostic technologies and effective interventions.[13,14] The main causes of visual deterioration in DM are diabetic macular edema[15] and vitreous hemorrhage. Visual impairment places the individual in a situation that can profoundly affect their quality of life. It has been integrated with insurmountable burdens like reduced physical activities,[16] social isolation,[17] role difficulties, dependency, and psychological disturbances.

Improving the quality of life is a primary goal while treating patients with DR so it becomes important to study the impact of DR on patients' quality of life through a validated assessment tool. In this study, we opted NEI-VFQ 25 questionnaire as it meets the required criteria of measuring several crucial qualitative features, including the impact of vision on everyday activities, emotional well-being, social relationships, and dependency.

The first approach to health-related QOL in the field of diabetes was made through the assessment of health status. The mean general health score was compared between two groups and was found to be highly significant ($p<0.001$). Diabetic patients with no DR had better general health as compare to patients with diabetic retinopathy. Just only the presence of diabetic retinopathy poses significant burden on patients due to emotional stress and frequent follow-ups. Our results are strengthened by the Los Angeles Latino Eye Study in which a large sample of Hispanic patients with Type 2 diabetes mellitus was studied regarding the impact of DR and its severity on quality of life.

The results of the study showed that the patients with DR had lower scores on the National Eye Institutes Visual Function Questionnaire.[18] However, there are some studies showing moderate or no significant effect of diabetic retinopathy on patients' quality of life. Wood Cock reported moderate quality of life in majority of patients with diabetic retinopathy,[19] and Leonyin Germany reported well to moderate quality of life.[20] In contrast Haninen et al. in Russia showed that no effect on quality of life in these patients.[21] The difference in results of these studies could be due to geographic, climatic, lifestyle and cultural differences that affect individual's perception of quality of life. Moreover different scales used for measuring quality of life in different studies could be another reason.

Next, General vision score was also found to be statistically significantly lower in case group. Among the case group, the patients with higher grade of DR and patients with CSME had much lower scores than rest of the patients. Similar results were determined in a study on 104 patients with NPDR and PDR with the aid of two measuring scales: NEI VFQ-25 and Vision Preference Value Scale (VPVS). Here patients with PDR suffered a greater loss of points than NPDR patients.[22] The study conducted by Alcubierre et al. In Germany also concluded that severity and degree of retinopathy have a negative effect on patients' quality of life. [23]

Any degree of visual affliction negatively influences the quality of life in diabetic patients. Vision related subscales like distant vision, near vision, colour vision, peripheral vision were recorded by documenting the difficulties faced by the patients during various tasks like cooking, sewing, reading newspaper, watching TV, viewing street signals, recognizing people in dim light, colour matching of the clothes, noticing the objects offside while walking etc. Reduced visual acuity among case group was linked with lower scores for the above activities ($p <0.001$). Colour vision was significantly affected in patients with macula involving diabetic retinopathy whereas the mean score of colour vision was 100 among the control group. Peripheral vision subscale score was also 100 among control group whereas it was found to be low among patients of PDR and Very severe NPDR who had undergone PRP treatment.

Similar results were found by the study conducted by Trento et al., which evaluates the quality of life in connection with vision in 196 patients of DR.[24]

Case group also endorsed significantly ($p<0.001$) lower scores regarding subscales ocular pain, social functioning, mental health, role difficulties and dependency indices. Not surprisingly, advance form of diseases like severe NPDR, PDR and CSME associated DR had poor impact on every aspect of patients' life both psychologically and functionally.[25-27] The therapeutic approach like anti -VEGF injections and PRP performed in advanced form of diabetic retinopathy are accompanied by more ocular discomfort as well as financial burden.

Driving subscale score was much lower among all subscales in both the groups though it was significantly lower in case group. This subscale might not have been assessed accurately as most the patients did not know driving skills or they use public transport.

Regarding limitations of this study, firstly the assessment of patients was based only on self-report, one-time questionnaire so response and recall bias may have been introduced.

Additionally, the fact that diabetes duration is a major factor in the development of DR caused a discrete bias in age distribution with a lower proportion of younger patients in the DR group.

5. Conclusion

The results of our study suggest that diabetic retinopathy has significant decremental impact on quality of life of patients with diabetes. The advanced forms of diabetic retinopathy pose a greater visual threat and thus worsens the patient's

quality of life in terms of various aspects like physical, psychological, emotional and financial. Therefore, our study can help to acquire a better understanding of the degree of social and emotional impact of DR, thus assisting policy planners, rehabilitation counselors and researchers in developing strategies for quality-of-life improvements in patients with DR.

6. Source of Funding

None.

7. Conflict of Interest

There are no conflicts of interest.

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