

## ORIGINAL ARTICLE

# Assessment of quality of life of the patients with diabetic retinopathy using National Eye Institute Visual Functioning Questionnaire (VFQ-25)

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**KEYWORDS**

Diabetes;  
Retinopathy;  
Quality of life

**Abstract**

**Background:** Diabetes affects most of the organs causing macrovascular and microvascular complications. Diabetic retinopathy (DR) results from the prolonged uncontrolled hyperglycemia which causes impairment of vision. Quality of life (QoL) of patients with DR is affected due to vision loss. National Eye Institute Visual Functioning Questionnaire (NEI-VFQ-25) is the questionnaire used to study the effect of DR on QoL.

**Objectives:** To assess the QoL of the patients with DR.

**Materials and methods:** The study enrolled 149 (male-104 and female 45) patients with DR. The previous translated and validated version of NEI-VFQ-25 questionnaire was used in the study.

**Results:** Cronbach alpha for internal consistency was between 0.6 and 0.8. The male patient showed significantly higher ( $p < 0.05$ ) QoL scores ( $60.73 \pm 1.63$ ) as compared to the female patients ( $53.15 \pm 2.84$ ). Hypertensive patients showed poor QoL as compared to non-hypertensive patients. The patients with a history of diabetes for 16–30 yrs. showed better QoL as compared to other patients.

**Conclusion:** DR affects the QoL of life of patients. Routine assessment of QoL using NEI-VFQ-25 questionnaire would be useful for physicians and health care team.

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**PALABRAS CLAVE**

Diabetes;  
Retinopatía;  
Calidad de vida

**Resumen**

**Antecedentes:** La diabetes afecta a la mayoría de los órganos provocando complicaciones macrovasculares y microvasculares. La retinopatía diabética (RD) es el resultado de la hiperglucemia incontrolada prolongada que causa deterioro de la visión. La calidad de vida (CdV)

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de los pacientes con RD se ve afectada debido a la pérdida de visión. El Cuestionario de funcionamiento visual (VFQ-25) es el cuestionario que se utiliza para estudiar el efecto de la RD en la calidad de vida.

**Objetivos:** Evaluar la CV de los pacientes con RD.

**Materiales y métodos:** El estudio reclutó a 149 (hombres-104 y mujeres 45) pacientes con RD. En el estudio se utilizó la versión anterior traducida y validada del cuestionario VFQ-25. Resultados El alfa de Cronbach para la consistencia interna estuvo entre 0,6 y 0,8. El paciente masculino mostró puntuaciones de calidad de vida significativamente más altas ( $p < 0,05$ ) ( $60,73 \pm 1,63$ ) en comparación con las mujeres ( $53,15 \pm 2,84$ ). Los pacientes hipertensos mostraron una calidad de vida deficiente en comparación con los pacientes no hipertensos. Los pacientes con antecedentes de diabetes de 16 a 30 años. mostró una mejor calidad de vida en comparación con otros pacientes.

**Conclusión:** El cuestionario VFQ-25 sería útil para que los médicos y el equipo de atención médica evalúen y mejoren la calidad de vida de los pacientes con RD.

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## Introduction

India is leading the world with the highest prevalence of diabetic patients with prevalence of 21.7%.<sup>1</sup> Diabetes is a disease which kills slowly by causing harm to the vital organs leading to diabetic macro and microvascular complications like neuropathy, nephropathy, and retinopathy, etc. Diabetic retinopathy (DR) results in ocular disturbances and loss of vision.<sup>2</sup> This greatly affects the day-to-day of DR patient's lifestyle and negatively affecting their QoL. The routine assessment of the QoL may also have clinical uses at the individual patient level. The results of the QoL study guides fostering patient-provider communication, identifying frequently overlooked problems, and prioritizing problems. The study aims to assess health-related quality of life of Indian DR patients.

## Materials and methods

### NEI-VFQ-25 questionnaire

The original NEI-VFQ-25 is a reliable and valid questionnaire. It is a self-administered general questionnaire designed to measure vision function in patients with chronic eye diseases like diabetic retinopathy, cataract, macular edema and glaucoma, etc. The NEI-VFQ-25 questionnaire has 25 items.<sup>3</sup> The items of the NEI-VFQ-25 form a subset of the 13 items. Response to each item measures the score from 1 to 6 according to the level of difficulties faced. Some questions are reversed to avoid bias.

In this cross-sectional study, the translated Hindi version of NEI-VFQ-25 questionnaire was used. Initial content, face and linguistic validation was performed in part 1 of the study.

### Study population

Total 149 patients with DR were enrolled from PBMA's H. V Desai eye hospital, Hadapsar, Pune, India.

### Ethical committee approval

The study was approved by the Institutional Ethics Committee, PBMA's H.V. Desai Eye Hospital, Hadapsar, Pune.

### Study duration

The study was conducted for a period of six months from August 2015 to April 2016 after ethical committee approval.

### Inclusion and exclusion criteria

The patients were selected based on the following inclusion and exclusion criteria:

#### Inclusion criteria

- 1) Patient with age 18 years or above.
- 2) Patient with diabetes type1 or type 2.
- 3) Patient with diabetic retinopathy.
- 4) Patient who can read and write Hindi language.
- 5) Patient ready to give informed consent.

#### Exclusion criteria

- 1) Patient with any other eye illness.
- 2) Patient with any other chronic disease.

### Patient consent

Initially, the patient information sheet was given to the patients. The need, importance and the purpose of the study

was explained to the patients. The patient consent was obtained confirming their willingness to participate in the study. The case record form was filled out by the investigator by questioning the patients verbally and from case report file. The questionnaire was then administered to the patients when they were waiting to meet the physician in the appointment area. Patients were asked to fill and complete the questionnaire. Filled questionnaire was checked for any missing data and the filled questionnaire was then collected from the patients.

### Statistical analysis

Graph Pad Prism (Version 7.0), Analytics with R (Version 3.2.3) software was used to perform statistical analysis. The test–retest reliability was evaluated using the Paired *t*-test. Internal consistency of the scale was examined by calculating the Cronbach's alpha. One-way ANOVA was used for multiple comparison analysis. Pearson's correlation coefficient was calculated for all the domains of the questionnaire.

### Questionnaire scoring

All items were scored. High score represents better functioning. Each item was then converted to a 0–100 scale so that the lowest and highest possible scores are set at 0 and 100 points, respectively.

### Results

In this cross-sectional study, total 149 DR patients were enrolled. The demographic variables of the DR patients were studied based on gender, age group, body weight, type of diabetes, blood glucose level, duration of diabetes, hypertension, smoking, type of retinopathy. The details of demographic characteristics are listed in [Table 1](#).

### Cronbach's alpha for reliability study

The Cronbach's alpha was calculated for individual domains as well as for the total domains. Cronbach's alpha in the range of 0.7–0.9 indicates good internal consistency. The Cronbach's alpha for all the items was found to be 0.85 indicating good internal consistency of the NEI-VFQ-25 instrument. The domains general health, ocular pain, distant activities, social functioning, role difficulties, dependency, driving, peripheral vision showed good internal consistency. The domains general vision, near activities, mental health, color vision showed less Cronbach's alpha value. The results are represented below in [Table 2](#).

### Pearson's correlation between the domains of NEI-VFQ-25

Pearson's correlation coefficient was calculated for the total population. The Pearson correlation coefficient was used to measure the strength of a linear association between the domains of NEI-VFQ-25. The calculated Pearson's correlation coefficient ranged from 0.1 to 1.4. Significant positive relationship was observed between the domain's general health

**Table 1** Demographic profile.

Sr. no	Particular	No. of patients	%
1.	<i>Gender</i>		
	Male	104	70
	Female	45	30
2.	<i>Age (yrs.)</i>		
	40–50	20	14
	51–60	45	30
	61–70	64	43
	71–80	17	11
	81–90	03	02
3.	<i>Blood glucose level (mg/dl)</i>		
	150–250	128	86
	251–350	15	10
	351–400	01	03
	451–550	05	01
4.	<i>Type of diabetes</i>		
	Type 1	106	29
	Type 2	43	71
5.	<i>Duration of diabetes (yrs.)</i>		
	0–20	125	84
	21–40	22	15
	41–60	02	01
6.	<i>Hypertension</i>		
	Yes	86	58
	No	63	42
	<i>Smoking status</i>		
	Yes	18	12
	No	131	88
7.	<i>Type of diabetic retinopathy</i>		
	Type 1	12	08
	Type 2	27	18
	Type 3	09	06
	Type 4	101	68

**Table 2** Cronbach alpha values.

Domains	Cronbach's alpha	
	Test	Retest
General health (GH)	0.71	0.73
General vision (GV)	0.66	0.67
Ocular pain (OP)	0.81	0.81
Near activities (NA)	0.61	0.65
Distance activities (DA)	0.78	0.79
Social functioning (SF)	0.72	0.73
Mental health (MH)	0.66	0.68
Role difficulties (RD)	0.75	0.76
Dependency (DP)	0.84	0.84
Driving (DR)	0.81	0.84
Color vision (CV)	0.69	0.68
Peripheral vision (PV)	0.89	0.88
Total	0.85	0.87

**Table 3** Pearson's correlation between the domains of NEI-VFQ-25.

Domains	GH	GV	OP	NA	DA	SF	MH	RD	DP	DR	CV	PV
GH	1	0.39	0.88	-0.13	-0.13	0.92**	0.11	0.76	0.28	0.24	0.25	0.21
GV		1	0.15	1.01**	0.96**	0.14	0.47	0.98**	0.89	0.68	0.36	0.77
OP			1	0.25	-0.12	0.56	0.36	0.18	-0.12	0.85	0.22	0.15
NA				1	0.48	-0.12	0.10	0.95**	0.74	0.48	0.11	0.63
DA					1	0.23	0.18	0.75	0.68	0.78	0.32	0.29
SF						1	1.16	1.40	-0.99**	0.36	0.47	0.22
MH							1	0.15	0.58	0.74	0.08	0.39
RD								1	1.32**	0.23	0.87	0.77
DP									1	0.77	0.36	0.87
DR										1	0.18	0.88
CV											1	0.40
PV												1

**Table 4** Scores based on diabetes treatment.

Diabetes medications	Insulin (n = 43)	Sulfonyl- ureas (n = 21)	Bi- Guanides (n = 20)	Sulfonylureas + Alpha glucosidase Inhibitors (n = 11)	Sulfonylureas + Biguanides (n = 30)	Sulfonylureas + Gliptins + Biguanides (n = 24)
Scores	62.78 ± 10.96	59.17 ± 11.89	52.54 ± 12.79*	64.87 ± 14.82	62.17 ± 17.38	66.93 ± 18.54

Note: Values are expressed as Mean ± SD. High scores indicate good QoL.

\* Indicates  $p < 0.05$  as compared to sulfonylureas + gliptins + biguanides.

and social functioning. Positive relationship was observed between the domains general vision and near activities. The results are represented below in [Table 3](#).

#### Assessment of QoL of diabetic retinopathy patients

QoL scores for males and females were calculated. Females showed significantly low ( $53.15 \pm 2.84$ ) QoL score ( $p < 0.05$ ) as compared to males ( $60.73 \pm 1.63$ ).

**Scores based on age group.** QoL scores based on age group of patients were calculated. Patients with age group 81–90 yrs. showed the highest QoL score ( $62.8 \pm 6.92$ ) followed by age group of 51–60 yrs., 61–70 yrs. and 71–80 yrs. ( $60.01 \pm 18.83$ ,  $59.54 \pm 16.89$  and  $54.41 \pm 18.78$ ). Patients with age group of 40–50 yrs. had the lowest score ( $54.17 \pm 18.38$ ).

**QoL scores based on body weight.** QoL scores based on body weight were calculated. Patients with body weight 81–100 kg showed the highest score ( $74.37 \pm 15.95$ ), followed by patients with body weight 101–120 kg ( $66.80 \pm 0.00$ ) and 40–60 kg ( $58.05 \pm 18.63$ ). Patients with body weight 61–80 kg showed the lowest score ( $57.44 \pm 16.84$ ). High scores indicated good QoL.

**QoL scores based on history of smoking.** QoL scores of patients with and without history of smoking were calculated. Patients with no history of smoking showed higher score ( $59.05 \pm 17.04$ ) compared to patients with history of smoking ( $53.97 \pm 22.32$ ).

**QoL scores based on type of diabetes.** QoL scores based on type of diabetes were calculated. No significant difference was observed between QoL of patients with Type 1 and Type 2 diabetes ( $57.67 \pm 16.41$  and  $58.75 \pm 18.33$ ).

**QoL scores based on diabetes treatment.** QoL scores based on diabetes treatment were calculated. Patients with biguanides treatment showed significantly low score ( $p < 0.05$ ) compared to patients with sulfonylureas + gliptins + biguanides treatment. Patients with sulfonylureas + gliptins + biguanides treatment showed the highest score followed by sulfonylureas + alpha glucosidase inhibitors, insulin, sulfonylureas + biguanides, sulfonylureas. Patients with biguanides treatment alone showed the lowest score. QoL scores based on diabetes treatment are represented below in [Table 4](#).

**QoL scores based on type of retinopathy.** QoL scores based on type of retinopathy were calculated. Patients with Type 4 retinopathy showed significantly low ( $45.08 \pm 22.41$ ) score ( $p < 0.05$ ) as compared to patients with Type 1 retinopathy ( $62.08 \pm 11.37$ ).

Patients on the treatment of Avastin showed significantly high ( $p < 0.01$ ) quality of life scores ( $62.10 \pm 10.77$ ) as compared to the patients receiving laser treatment ( $47.36 \pm 14.75$ ).

QoL scores based on visual parameters were calculated. Patients with no PL vision showed significantly low score ( $p < 0.001$ ) as compared to the patients with vision in the range 6/60–6/6. Patients with vision in the range 6/36–6/6 showed the highest score followed by patients with PL PR, HM+, HM–. Patients with no PL vision showed the lowest score. QoL scores based on visual parameters are represented below in [Table 5](#).

**NEI-VFQ-25 scores in different diabetic retinopathy populations.** Scores for individual domains and the total domains were calculated separately in current population.

**Table 5** Scores based on visual parameters.

Vision	6/60–6/6 (n = 62)	HM+ (n = 30)	HM– (n = 27)	PL PR (n = 15)	No PL (n = 15)
Score	68.36 ± 11.63	54.12 ± 14.85	52.24 ± 12.78	62.18 ± 10.43	45.23 ± 11.97**

Note: Values are expressed as Mean ± SD. High scores indicate good QoL.

\*\* Indicates  $p < 0.001$  as compared to 6/60–6/6.

HM+: Hand movement positive, HM–: Hand movement negative, PL PR: Perception of light and projection of rays, No PL: No perception of light.

**Table 6** NEI-VFQ-25 scores in different diabetic retinopathy populations.

Domains	Current study (n = 149)	Mangione et al. (n = 123)	Cusick et al. (n = 170)
General health	32.18 ± 10.12	46 ± 25	50 ± 2
General vision	25.06 ± 11.12**	62 ± 21	72 ± 1.3
Ocular pain	63.78 ± 12.36	88 ± 17	93 ± 1.1
Near activities	31.63 ± 15.63*	36 ± 30	78 ± 1.9
Distant activities	62.45 ± 11.89	66 ± 30	77 ± 1.9
Social functioning	78.25 ± 18.37	81 ± 26	93 ± 1.3
Mental health	56.25 ± 14.39	66 ± 29	77 ± 1.9
Role difficulties	46.36 ± 13.92*	69 ± 31	81 ± 1.9
Dependency	66.31 ± 12.83	77 ± 30	87 ± 1.8
Driving	52.79 ± 10.87	55 ± 40	79 ± 2.0
Color vision	79.67 ± 11.54	90 ± 22	90 ± 1.6
Peripheral vision	61.96 ± 16.97	78 ± 29	82 ± 2.0
Composite score	54.72 ± 17.84	67.83 ± 16.39	79.91 ± 11.59

\* Indicates  $p < 0.05$  as compared to Cusick et al.

\*\* Indicates  $p < 0.01$  as compared to Cusick et al.

Values are expressed as Mean ± SD. High scores indicate good QoL.

The score of domain general vision in current study was observed to be significantly low ( $p < 0.001$ ) as compared to the scores of the study of Cusick et al. The score of domains near activities in current study was observed to be significantly low ( $p < 0.05$ ) as compared to scores of the study of Cusick et al. The score of domain role difficulties in current study was observed to be significantly low ( $p < 0.05$ ) as compared to the scores of the study of Cusick et al. The composite score of current study was observed to be significantly low ( $p < 0.001$ ) compared to the composite score of the study of Cusick et al. The NEI-VFQ-25 scores are represented below in Table 6.

## Discussion

The objective of the study was to assess the QoL of DR patients. The differences in QoL according to age, gender, duration of disease, duration of diabetes, visual parameters treatment and severity of retinopathy was studied. The psychometric properties of the NEI-VFQ-25 were found to be robust for the different eye conditions in previous studies suggesting the reproducibility of the measure if used across multiple conditions of different severity of eye diseases.<sup>4</sup> Cronbach's alpha for all the domains was calculated and was found to be 0.85 supporting the internal consistency of NEI-VFQ-25 questionnaire. No significant difference ( $p > 0.05$ ) in the test and retest scores was observed after the test-retest (after a period of 3 weeks ± 3 days). The male patients

showed significantly higher QoL score as compared to the female patients. Hypertensive patients showed poor QoL as compared to non-hypertensive patients. The patients with history of diabetes for 16–30 yrs. showed better QoL as compared to other patients. However, no significant difference was observed between the scores of patients based on the duration of diabetes. Patients with Type 1 retinopathy showed the highest score compared to other types of retinopathy. In previous study, the burden of diabetic DR and diabetic macular edema (DME) was studied on QoL in type 1 and type 2 diabetic patients using the Euro QoL EQ-5D generic multi-attribute utility instrument (MAUI).<sup>5</sup> The findings of the study suggested that the EQ-5D lacks sensitivity to capture the impact of the severity of DR/DME on QoL domains. No significant difference was observed in the scores of patients based on the duration of DR. Turkish version of NEI-VFQ-25 was studied for measuring VR QoL in 93 DR patients. Composite NEI-VFQ-25 score was found to be significantly higher in patients with shorter duration of DM and who had a better visual acuity.<sup>6</sup>

The patients prescribed with sulfonylureas + gliptins + biguanides showed significantly highest QoL as compared to patients using other medications for diabetes management. The patients with Avastin treatment for DR showed significantly higher QoL as compared to patients who had undergone the laser treatment.

Patients with vision in the range 6/60–6/6 showed significantly higher score as compared to patients with no perception of light vision. The NEI-VFQ-25 scores for all the



domains were calculated separately in current population. The score was found to be the lowest in the domain general vision and it was found to be the highest in the domain social functioning. The scores for current study were compared to the two previous studies conducted in the US population.<sup>3,7</sup> The different results in these previous studies may be due to geographic, climatic, lifestyle and cultural differences has affected the individual's perception of QoL. To study the impact of diabetic retinopathy on QoL an item bank development project was undertaken to study the qualitative aspects of QoL of DR patients.<sup>8</sup>

Due to the non-availability of NEI-VFQ-25 in any of the Indian languages, there were not many studies done in Indian population, which led to the disease progression and worsening of QoL, which needs to be studied. The current study showed that the QoL of patients with DR varies according to gender, type of DR, hypertension, diabetes medications, DR treatment, visual parameters. Diabetes medications also affects QoL in patients with DR. Hence, medical practitioners should make the best choices in selecting the medications to promote patient care. It is recommended that authorities adopt consulting and training to control the predictors of QoL and improve patients' QoL. The study will be useful to design health policies for the treatment of DR while focusing on all the important aspects of QoL. The study provide insight to the problems associated with the QoL of Indian DR patients and has raised the question to be answered on how the current clinical practice can include routine assessment of QoL to decrease the disease burden.

## Conclusion

QoL of Indian DR patients is negatively affected. All the factors related to the demography, the severity of disease and drug treatment affects the QoL of DR patient and should be assessed. The routine QoL assessment will definitely support physicians to decide the line of treatment that suits best to the patient. This will further improve the health outcome and the quality of management of health services.

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## Conflict of interest

Authors declare no conflict of interest.

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