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# Association between quality of life and visual characteristics in individuals with diabetic retinopathy

**Rikta Paul[1], Sourav Karmakar[1], Susmita Banerjee[2]**

*[1]Swami Vivekananda University, School of Allied Health Sciences, Department of Optometry, West Bengal, India*
*[2]Dr. D. Y. Patil Vidyapeeth, Pune, (Deemed to be University), Institute of Optometry and Visual Sciences, Maharashtra, India*

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**Corresponding Author:**
Rikta Paul, M.OPTOM, Swami Vivekananda University, School of Allied Health Sciences, Department of Optometry, West Bengal, India
+09742314793
riktapaul48@gmail.com

**ORCID:**
orcid.org/0000-0002-1740-9852

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## ABSTRACT

**Aims:** To estimate the vision-targeted quality of life (QoL) in diabetic retinopathy (DR) patients and further correlate the National Eye Institute-Visual Functioning Questionnaire-25 (NEI-VFQ-25) score with demographic factors and visual function parameters.

**Methods:** This cross-sectional observational study included 92 patients with type 2 DR. The Marathi version of the NEI-VFQ-25 was used to assess QoL. Visual acuity (VA) for distance and near vision was assessed using the logMAR distance and near acuity chart, contrast sensitivity (CS) was assessed using a Pelli-Robson chart, and color vision was assessed using the Ishihara chart.

**Results:** The mean age was 65.08±17.56 ranging from 40 to 84 years participated in the study. Of the 92 patients with DR, 55.43% were male and 44.56% were female. The mean distance VA of the better eye was 0.7±0.29 logMAR. The mean near VA was 0.43±0.29 logMAR. The mean CS for the better eye was 0.95±0.50 log. The mean NEI-VFQ-25 composite score was 65.08±17.07. The subscales most affected were general health (50.7±20.16), mental health (52.22±25.03), and general vision (52.99±19.9).

**Conclusions:** QoL was significantly lower among patients with DR. Mental health, general health, general vision, and near vision were mostly affected. There was a significant association between the NEI-VFQ-25 score and age. The NEI-VFQ-25 score decreased with increasing age. Visual function parameters, including distance VA, near VA, and CS, were significantly associated with the NEI-VFQ-25 score.

## Introduction

Diabetic retinopathy (DR) is a common complication of long-term and inadequately controlled diabetes mellitus (DM) (1). It is responsible for blindness and vision loss in individuals aged 60 years (2). It causes restrictions such as visual impairment, socially independent functional loss of work productivity, and economic loss due to treatment costs (3).

Impairment of vision and treatment costs due to DR can greatly impact patients' quality of life (QoL) and compel severe economic strain on society (4). Assessing health-related QoL (HR-QoL) provides better insight into the influence of disease and its treatment from a patient's viewpoint, which is not exposed in clinical assessment. Measuring QoL in affected individuals is highlighted in a patient-centric healthcare prototype (5).

In recent years, researchers in the health sciences have illustrated the imperative function of QoL in managing patients with diabetes. Worldwide, different studies in the past have revealed contradictory outcomes regarding QoL in these patients (6). According to previous studies, DR does not affect QoL (7,8). Nevertheless, some researchers have stated that there is a significant effect of visual impairment due to DR on patients' QoL (9-11). Therefore, determining QoL in patients with DR from different geographical locations is critical. Despite the ambiguity of obtaining the National Eye Institute-Visual Function Questionnaire-25 (NEI-VFQ-25) in the Indian language, few studies have been conducted in the Indian population, leading to disease and deteriorating QoL, which must be investigated. In a previous study using the Hindi translation of the NEI-VFQ-25, researchers from Pune found that DR negatively affects QoL (12). Although Marathi is Maharashtra's most widely spoken language, research on the QoL of people with DR in Pune, Maharashtra, has yet to be published using the Marathi-translated NEI-VFQ-25. This is the first study to assess VR-QoL in patients with DR from Pune, Maharashtra, employing the Marathi variant of the NEI-VFQ-25 and correlating these results with visual parameters. To evaluate vision-targeted QoL in patients with DR, to assess visual acuity (VA) and contrast sensitivity (CS), which are further correlated with the NEIVFQ-25 score.

## Methods

### Study design and setup

From January to March 2022, a cross-sectional observational study was conducted at the tertiary eye hospital. The study followed the Declaration of Helsinki, and the Institutional Review Board and Ethics Committee of Dr. D. Y. Patil Vidyapeeth provided ethical approval (re-reg. No. ECR/361/Inst/MH/2013/RR-16, date: 27.11.2019) for the study. The study involved 92 individuals diagnosed with type 2 diabetes and DR who met specific inclusion criteria. Additionally, the participants were required to provide informed consent and adhere to the study's prescribed protocol. Type 2 diabetes diagnosis was confirmed by thoroughly examining the patients' medical records. To be included in the study, the participants had to maintain stable glycemic control for 3 months, as indicated by HbA1c levels not exceeding 8%. Individuals with a history of severe diabetic ketoacidosis or hyperosmolar hyperglycemic states within the last 12 months were excluded. DR was categorized using the Early Treatment Diabetic Retinopathy Study (ETDRS) grading system. Ocular diseases other than DR, which may affect visual parameters, were excluded, such as aphakia, significant cataract (the cataract has been graded, followed by the World Health Organization simplified Cataract Grading system), corneal pathology, glaucoma, vitreous pathology, and retinal and optic nerve pathology. Participants who were either unwilling to participate, declined to complete the questionnaire, or submitted incomplete questionnaires were excluded from the study.

Participants' cognitive capacity was assessed using the Mini-Mental State Examination, which evaluates memory, attention, and executive function based on a minimum score. To maintain a specific focus on individuals predominantly affected by DR, it was imperative to exclude patients with illnesses that significantly impair cognitive function, such as Alzheimer's disease and other neurodegenerative diseases.

Language barriers hindering assessment understanding and completion were also grounds for exclusion. Individuals who are prescribed certain drugs may experience visual impairment as a result of probable adverse reactions. The study did not include medications that have the potential to impact visual functionality, such as corticosteroids, anticholinergics, antidepressants, isotretinoin, beta-blockers, oral contraceptives, and digoxin.

### Data collection

Demographic information, such as age and gender, diabetes duration, and DR grade, was collected. Near VA (NVA), distant VA (DVA), and CS were examined and recorded. The ETDRS logarithm of the minimum angle of resolution (logMAR) chart was used to measure the best-corrected distance VA at a distance of 4 m. A standard retro-illuminator (the Lighthouse Chart lighting Unit from New York) was used for consistency of illumination. If the patients could not identify the peak line at a distance of four meters, the chart was moved by two and one meters until the patients achieved it. At a distance of 40 cm, the NVA was calculated as the smallest print that could be perceived by the patient with the finest corrective lenses using the logMAR NVA chart in an environment with controlled room illumination. A Pelli-Robson chart was employed to evaluate CS at a distance of 1 m and was tested binocularly to ensure that the chart luminance was within the manufacturer's recommended range of 60-120 cd/m$^2$. The Ishihara pseudoisochromatic plates, specifically plates 1-17, were used with all participants to detect any red-green color deficiency. This testing procedure was conducted under normal room lighting conditions at a distance of 75 cm, with participants using their best-corrected VA.

### Questionnaire

This study utilized a Marathi translation of the NEI-VFQ-25 to assess participants' QoL. Initially, the NEI-VFQ-25 included 51 components designed to evaluate the impact of ocular diseases on an individual's functional activities and overall well-being (13). Subsequently, a concise version comprising 25 components was introduced. The well-established NEI-VFQ-25 questionnaire has undergone successful translation and validation in numerous languages. Self-assessment of vision-related functions was measured across 11 dimensions in the NEI-VFQ-25. These dimensions encompass general health, general vision, ocular discomfort, close and distant activities,

driving, color vision, peripheral vision, social functioning, role challenges, and dependence. Face-to-face interviews were conducted by one of the investigators at the hospital's outpatient department, following a consistent questionnaire administration method. Patients typically required approximately 10-15 minutes to complete the survey.

### Statistical Analysis

Statistical Package for the Social Sciences 27.0.0 was used to perform all analyses on the collected data. Information was usually provided. The data followed a normal distribution. Descriptive statistics, independent t-tests, and analysis of variance (ANOVA) were used to compare the NEI-VFQ-25 composite scores between the groups. Pearson's correlation regression test was applied to illustrate the correlation between the NEI-VFQ-25 composite score and demographic (age and gender) and visual parameters (NVA, DVA, and CS).

## Results

A total of 107 individuals with type 2 DR were initially selected for the study. However, after the initial ophthalmic assessment, 6 patients refused to complete the questionnaire, and 9 patients did not fully fill out the questionnaire. To ensure the integrity and completeness of our data, we excluded participants. Finally, 92 patients were examined with a mean age of 65.08±17.56 years, ranging from 40 to 84. The analysis revealed notable demographic traits and varying degrees of disease severity among the participants. A slight male predominance (51, 55.43%) was observed compared with a female predominance (41, 44.56%). The age distribution was fairly distributed, with the 60-69 age group having the highest representation (27.08%), followed by a relatively balanced distribution across the 40-49, 50-59, and 70-79 age groups (21.73%, 20.65% and 22.82%). The 80-90-year-old age group comprised the smallest proportion (7.60%) of participants. In terms of diabetes duration, most participants had the disease for 11-21 years (45.79%), followed by those with a history of more than 21 years (34.57%) and those diagnosed within the last 1-10 years (19.62%). DR severity varied, with proliferative DR (PDR) being the most common (46, 42.99%), followed by severe non- PDR (NPDR) (20, 18.69%), moderate NPDR (15, 14.01%), and mild NPDR (11, 10.28%).

### Visual function

The mean DVA for the better eye was 0.7±0.29 logMAR, ranging from 0 to 1.3 logMAR. The mean NVA was 0.43±0.29 logMAR, ranging from 0 to 1.1 logMAR. The mean CS for the better eye was 0.95±0.50 log, ranging from 0.2 logs to 2.3 logs. Of the 92 patients, 81.31% had normal color vision, while 18.79% had color vision defects. The baseline characteristics of the visual functions are illustrated in Table 1.

### Cronbach's alpha score for consistency

All subscales were calculated using Cronbach's alpha. A Cronbach's alpha is between 0.7 and 0.9 indicates high internal consistency. All items had a Cronbach's alpha of 0.98, indicating that the NEI-VFQ-25 instrument was internally consistent.

### Score for the NEI-VFQ

The average NEI-VFQ-25 composite score was 65.08± 17.07. The most affected subscales were general health (50.7±20.16), mental health (52.22±25.03), general vision (52.99±19.9), near activities (55.61±27.81), and distance activities (58.60±21.75). However, the disease did not affect peripheral vision (82.24±21.72) and color vision (69.86±24.7). Higher scores were obtained for ocular pain (92.64±13.29) and driving (88.75±7.86). The NEI-VFQ-25 scores of the different subscales are illustrated in Table 2. The composite scores of different age groups and DR types are presented in Table 3. The difference in composite scores between age categories and types of DR was statistically significant (p=0.001).

**Table 1. Baseline characteristics of the study participants**

| Visual functions | Mean, SD |
|---|---|
| DVA (logMAR) | 0.7±0.29 |
| NVA (logMAR) | 0.43±0.29 |
| CS (log) | 0.95±0.50 |
| **Color vision** | **Frequency and percentage** |
| Normal | 75 (81.31%) |
| Defective | 17 (18.79%) |

DVA: Distance visual acuity, NVA: Near visual acuity, CS: Contrast sensitivity, SD: Standard deviation

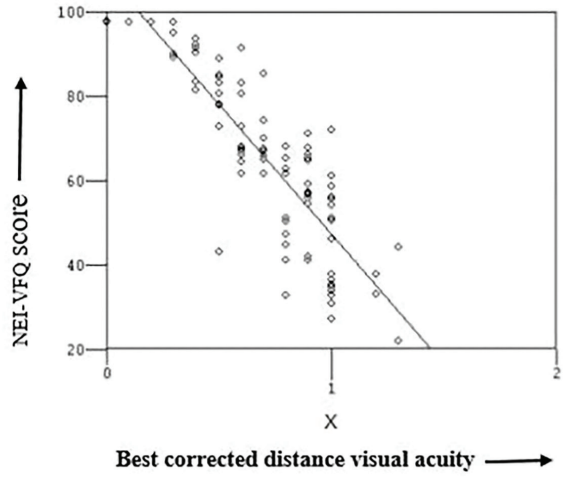


**Figure 1.** Correlation between NEI-VFQ and near visual acuity
NEI-VFQ: National Eye Institute-Visual Functioning Questionnaire

**Association between NEI-VFQ-25 and demographic characteristics and visual functions**

Demographic factors like age significantly correlated with the NEI-VFQ-25 composite score, whereas gender showed no significant correlation (Table 4). The NEI-VFQ-25 composite score demonstrated a notable link with DVA, NVA, and CS. Figure 1 illustrates a robust inverse relationship between DVA and the NEI-VFQ-25 score, indicating that as the logarithmic value of VA decreases, the NEI-VFQ-25 score increases. Conversely, Figure 2 presents a substantial correlation between CS and the NEI-VFQ-25 score, suggesting that an increase in the logarithmic measure of CS corresponds to an elevation in the NEI-VFQ-25 score. The better the VA, near vision, and CS were, the better the mean composite score.

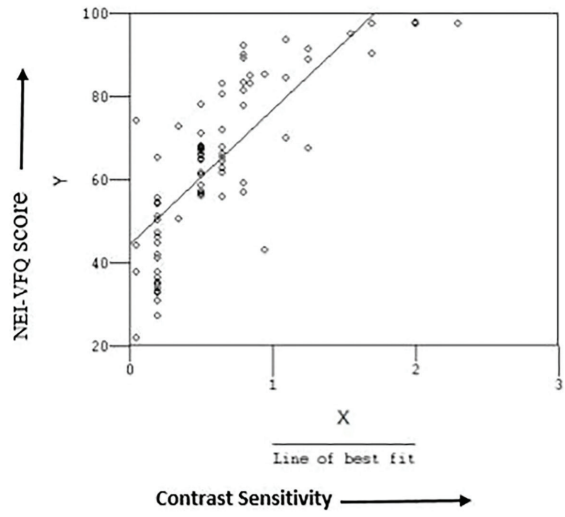


**Figure 2.** Correlation between NEI-VFQ and best-corrected distance visual acuity

NEI-VFQ: National Eye Institute-Visual Functioning Questionnaire

**Table 2. Mean and standard deviation of NEI-VFQ-25 scores among the Indian populations**

| Domains | Present study (n=107) | Pawar et al. (12) (n=149) | Pereira et al. (20) (n=123) |
|---|---|---|---|
| **General health** | 50.7±20.16 | 32.18±10.12 | 58.43±14.59 |
| **General vision** | 52.99±19.9 | 25.06±11.12 | 63.69±19.26 |
| **Ocular pain** | 92.64±13.29 | 63.78±12.36 | 89.10±13.32 |
| **Near activities** | 55.61±27.37 | 31.63±15.63 | 70.79±30.56 |
| **Distance activities** | 58.6±21.75 | 62.45±11.89 | 72.68±32.41 |
| **Social functioning** | 69.04±24.36 | 78.25±18.37 | 78.69±24.15 |
| **Mental health** | 52.22±25.03 | 56.25±14.39 | 71.71±28.77 |
| **Role difficulties** | 58.07±25.08 | 46.36±13.92 | 74.80±27.97 |
| **Dependency** | 59.66±26.08 | 66.31±12.83 | 77.17±27.93 |
| **Driving** | 88.75±7.86 | 52.79±10.87 | 48.84±42.63 |
| **Color vision** | 69.86±24.7 | 79.67±11.54 | 76.29±28.27 |
| **Peripheral vision** | 82.24±21.72 | 51.96±16.97 | 73.93±25.55 |
| **Composite score** | 65.08±17.07 | - | 73.93±25.55 |

NEI-VFQ-25: National Eye Institute-Visual Functioning Questionnaire-25

**Table 3. Comparison of the NEI-VFQ-25 scores of demographic variables**

| Age group (years) | Composite score | p value |
|---|---|---|
| **Gender** | | |
| **Male** | 65.28±17.56 | p=0.69 |
| **Female** | 64.82±17.88 | |
| **Age group** | | |
| **40-49** | 90.00±11.95 | |
| **50-59** | 73.00±15.19 | |
| **60-69** | 60.24±18.80 | p=0.0001 |
| **70-79** | 48.48±23.21 | |
| **80-90** | 34.14±21.98 | |
| **Severity of DR** | | |
| **Mild NPDR** | 94.52±2.99 | |
| **Moderate NPDR** | 84.58±6.68 | |
| **Severe NPDR** | 75.87±8.90 | p=0.001 |
| **PDR** | 51.44±12.96 | |

NEI-VFQ-25: National Eye Institute-Visual Functioning Questionnaire-25, DR: Diabetic retinopathy, NPDR: Non-PDR, PDR: Proliferative DR

**Table 4. Association between the NEI-VFQ-25 composite score with demographic parameters and visual functions**

| **Correlation between NEI-VFQ-25 scores and demographic parameters** | | |
|---|---|---|
| **Demography** | **Correlation coefficient** | **p values** |
| Age | -0.87 | 0.001 |
| Gender | -0.012 | 0.9 |
| Severity of DR | -0.80 | 0.001 |
| Duration of DM | -0.81 | 0.001 |
| **Correlation between NEI-VFQ-25 and visual function** | | |
| **Visual function** | **Correlation coefficient (r)** | **p values** |
| DCVA | -0.85 | 0.001 |
| NVA | -0.86 | 0.001 |
| CS | 0.79 | 0.001 |

NEI-VFQ-25: National Eye Institute-Visual Functioning Questionnaire-25, DR: Diabetic retinopathy, DM: Diabetes mellitus, DCVA: Distant corrected visual acuity, NVA: Near visual acuity, CS: Contrast sensitivity

## Discussion

The main findings of the current study are as follows; patients with DR exhibited significantly lower QoL. The disease had an impact on general health, mental health, overall vision, near activities, and distance activities. Color and peripheral vision were least affected. The NEI-VFQ-25 score was strongly correlated with age and visual function.

HR-QoL in patients with DR can be assessed using various tools (3,10). According to previous reports, the NEI-VFQ-25 is an excellent tool for measuring the VR-QoL of patients with DR because it captures the psychological and emotional aspects of the disease and the visual purpose (3,14).

Previously, the NEI-VFQ-25 was employed in diverse populations to assess the QoL of subjects with different diseases (15,16). Therefore, in the present study, we used the Marathi-translated NEI-VFQ-25 to evaluate VR-QoL in patients with DR. This study provides evidence regarding the influence of demographic factors, including age and gender, duration of DM and severity of DR, and visual parameters, including DVA, NVA, and CS, on VR-QoL in patients with DR. The current research showed that DR dramatically affects patients' QoL, primarily affecting general health, vision, and mental health.

According to previous studies, women with DR have a significantly lower QoL than men (12,17). In the current study, women scored less than men, although the difference was not statistically significant. In the current analysis, no significant association was identified between the NEI-VFQ-25 composite score and gender, similar to previous research (18,19). On the contrary, some studies have found lower QoL scores among females than males (12,17). These differences may be due to geographical distribution and cultural variations. Patients aged 40-50 years recorded the lowest QoL scores, according to Pawar et al. (12), whereas those aged 81-90 years reported the highest QoL. The current investigation revealed a negative relationship between the NEI-VFQ-25 composite score and age, consistent with previous studies (20,21). The severity of DR has a significant impact on QoL. As the severity of DR progresses, the NEI-VFQ-25 score shows significant deterioration. Previous studies on QoL scores between the NPDR and PDR groups found no significant differences (21,22). In the present study, the PDR group had significantly lower QoL scores than the NPDR group, similar to a study by Pereira et al. (20). The duration of DM was significantly correlated with the NEI-VFQ-25 composite score. Çetin et al. (22) and Pereira et al. (20) reported similar findings.

The current study showed that VA and NEI-VFQ-25 scores were significantly correlated with patients with DR. When VA was amplified, NEI-VFQ-25 scores were also amplified. This finding is similar to that of previous studies (12,22). Along with contributing to poor VA, poor scores on the NEI-VFQ-25 may indicate a lack of CS, as it has become a routine method for assessing visual function in a clinical setup further (23). The present study also revealed an association between CS and QoL. This finding supports the NEI-VFQ-25's validity for assessing visual function in individuals with DR.

According to the current study, general health was the most significantly affected by DR, followed by general vision and mental health. Pereira et al. (20) also reported the same findings in their study. Hence, the mere existence of DR in patients with diabetes significantly influences their overall health perception. The decrease in the overall vision rating is attributed to the intensity of DR. The fact that people with diabetes had DR influenced how they thought about their well-being. The mental health domain reflects concern, dissatisfaction, lack of control over events, and worry about possible stigma associated with vision.

Ocular pain had the highest mean value in the present study, which is consistent with previous research findings (8,20). Pereira et al. (20) reported that the driving subscale had the lowest average score; in the present study, a higher score in the driving subscale was obtained. The driving subscale was incorrectly estimated because of a low response rate; most individuals use public transportation (20).

There is not enough long-term follow-up in this study to track the development of DR and how it affects QoL over time. To fully comprehend the long-term effects of DR severity and changes in visual function on QoL, longitudinal research is required. Color vision defects may affect the CS. The current study did not assess the relationship between CS and the NEI-VFQ-25 score after excluding patients who had color-vision impairments, which could have affected the findings. Thorough ophthalmological examinations are required to eliminate these potential influences.

## Conclusion

Patients with DR had considerably worse QoL. The general vision, general health, and mental health subscales scored the lowest. The NEI-VFQ-25 score was significantly associated with age; with increasing age, the score decreased. Visual function parameters, including DVA, NVA, and CS, were significantly associated with the NEI-VFQ-25 score. Poorer the visual function, poorer the NEI-VFQ-25 score.

### Ethics

**Ethics Committee Approval:** The study followed the Declaration of Helsinki, and the Institutional Review Board and Ethics Committee of Dr. D. Y. Patil Vidyapeeth provided ethical approval (re-reg. No. ECR/361/Inst/MH/2013/RR-16, date: 27.11.2019) for the study.

**Informed Consent:** Consent form was filled out by all participants.

### Footnotes

### Authorship Contributions

Surgical and Medical Practices: R.P., S.K., S.B., Concept: R.P., S.K., S.B., Design: R.P., S.B., Data Collection or Processing: R.P., S.B., Analysis or Interpretation: R.P., S.K., Literature Search: R.P., S.K., S.B., Writing: R.P., S.K., S.B.

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